

107TH CONGRESS
2D SESSION

H. R. 4954

To amend title XVIII of the Social Security Act to provide for a voluntary program for prescription drug coverage under the Medicare Program, to modernize and reform payments and the regulatory structure of the Medicare Program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 18, 2002

Mrs. JOHNSON of Connecticut (for herself and Mr. BILIRAKIS) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XVIII of the Social Security Act to provide for a voluntary program for prescription drug coverage under the Medicare Program, to modernize and reform payments and the regulatory structure of the Medicare Program, and for other purposes.

1 *Be it enacted by the Senate and House of Representatives*
2 *of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SE-**
4 **CURITY ACT; REFERENCES TO BIPA AND**
5 **SECRETARY; TABLE OF CONTENTS.**

6 (a) SHORT TITLE.—This Act may be cited as the “Medi-
7 care Modernization and Prescription Drug Act of 2002”.

1 (b) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as
 2 otherwise specifically provided, whenever in this Act an amend-
 3 ment is expressed in terms of an amendment to or repeal of
 4 a section or other provision, the reference shall be considered
 5 to be made to that section or other provision of the Social Se-
 6 curity Act.

7 (c) BIPA; SECRETARY.—In this Act:

8 (1) BIPA.—The term “BIPA” means the Medicare,
 9 Medicaid, and SCHIP Benefits Improvement and Protec-
 10 tion Act of 2000, as enacted into law by section 1(a)(6) of
 11 Public Law 106–554.

12 (2) SECRETARY.—The term “Secretary” means the
 13 Secretary of Health and Human Services.

14 (d) TABLE OF CONTENTS.—The table of contents of this
 15 Act is as follows:

Sec. 1. Short title; amendments to Social Security Act; references to BIPA
 and Secretary; table of contents.

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

Sec. 101. Establishment of a medicare prescription drug benefit.

“PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

“Sec. 1860A. Benefits; eligibility; enrollment; and coverage period.

“Sec. 1860B. Requirements for qualified prescription drug coverage.

“Sec. 1860C. Beneficiary protections for qualified prescription drug
 coverage.

“Sec. 1860D. Requirements for prescription drug plan (PDP) spon-
 sors; contracts; establishment of standards.

“Sec. 1860E. Process for beneficiaries to select qualified prescription
 drug coverage.

“Sec. 1860F. Submission of bids.

“Sec. 1860G. Premium and cost-sharing subsidies for low-income indi-
 viduals.

“Sec. 1860H. Subsidies for all medicare beneficiaries for qualified pre-
 scription drug coverage.

“Sec. 1860I. Medicare Prescription Drug Trust Fund.

“Sec. 1860J. Definitions; treatment of references to provisions in part
 C.

Sec. 102. Offering of qualified prescription drug coverage under the
 Medicare+Choice program.

Sec. 103. Medicaid amendments.

Sec. 104. Medigap transition.

Sec. 105. Medicare prescription drug discount card endorsement program.

TITLE II—MEDICARE+CHOICE REVITALIZATION AND MEDICARE+CHOICE COMPETITION PROGRAM

Subtitle A—Medicare+Choice Revitalization

Sec. 201. Medicare+Choice improvements.

- Sec. 202. Making permanent change in Medicare+Choice reporting deadlines and annual, coordinated election period.
- Sec. 203. Avoiding duplicative State regulation.
- Sec. 204. Specialized Medicare+Choice plans for special needs beneficiaries.
- Sec. 205. Medicare MSAs.
- Sec. 206. Extension of reasonable cost and SHMO contracts.

Subtitle B—Medicare+Choice Competition Program

- Sec. 211. Medicare+Choice competition program.
- Sec. 212. Demonstration program for competitive-demonstration areas.
- Sec. 213. Conforming amendments.

TITLE III—RURAL HEALTH CARE IMPROVEMENTS

- Sec. 301. Reference to full market basket increase for sole community hospitals.
- Sec. 302. Enhanced disproportionate share hospital (DSH) treatment for rural hospitals and urban hospitals with fewer than 100 beds.
- Sec. 303. 2-year phased-in increase in the standardized amount in rural and small urban areas to achieve a single, uniform standardized amount.
- Sec. 304. More frequent update in weights used in hospital market basket.
- Sec. 305. Improvements to critical access hospital program.
- Sec. 306. Extension of temporary increase for home health services furnished in a rural area.
- Sec. 307. Reference to 10 percent increase in payment for hospice care furnished in a frontier area and rural hospice demonstration project.
- Sec. 308. Reference to priority for hospitals located in rural or small urban areas in redistribution of unused graduate medical education residencies.
- Sec. 309. GAO study of geographic differences in payments for physicians' services.
- Sec. 310. Providing safe harbor for certain collaborative efforts that benefit medically underserved populations.

TITLE IV—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

- Sec. 401. Revision of acute care hospital payment updates.
- Sec. 402. 2-year increase in level of adjustment for indirect costs of medical education (IME).
- Sec. 403. Recognition of new medical technologies under inpatient hospital PPS.
- Sec. 404. Phase-in of Federal rate for hospitals in Puerto Rico.
- Sec. 405. Reference to provision relating to enhanced disproportionate share hospital (DSH) payments for rural hospitals and urban hospitals with fewer than 100 beds.
- Sec. 406. Reference to provision relating to 2-year phased-in increase in the standardized amount in rural and small urban areas to achieve a single, uniform standardized amount.
- Sec. 407. Reference to provision for more frequent updates in the weights used in hospital market basket.
- Sec. 408. Reference to provision making improvements to critical access hospital program for more frequent updates in the weights used in hospital market basket.

Subtitle B—Skilled Nursing Facility Services

- Sec. 411. Payment for covered skilled nursing facility services.

Subtitle C—Hospice

- Sec. 421. Coverage of hospice consultation services.
- Sec. 422. 10 percent increase in payment for hospice care furnished in a frontier area.
- Sec. 423. Rural hospice demonstration project.

Subtitle D—Other Provisions

- Sec. 431. Demonstration project for use of recovery audit contractors for part A services.

TITLE V—PROVISIONS RELATING TO PART B

Subtitle A—Physicians’ Services

- Sec. 501. Revision of updates for physicians’ services.
- Sec. 502. Studies on access to physicians’ services.
- Sec. 503. MedPAC report on payment for physicians’ services.

Subtitle B—Other Services

- Sec. 511. Competitive acquisition of certain items and services.
- Sec. 512. Payment for ambulance services.
- Sec. 513. 1-year extension of moratorium on therapy caps; provisions relating to reports.
- Sec. 514. Accelerated implementation of 20 percent coinsurance for hospital outpatient department (OPD) services; other OPD provisions.
- Sec. 515. Coverage of an initial preventive physical examination.
- Sec. 516. Renal dialysis services.

TITLE VI—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

- Sec. 601. Elimination of 15 percent reduction in payment rates under the prospective payment system.
- Sec. 602. Establishment of reduced copayment for a home health service episode of care for certain beneficiaries.
- Sec. 603. Update in home health services.
- Sec. 604. OASIS Task Force; suspension of certain OASIS data collection requirements pending Task Force submittal of report.
- Sec. 605. MedPAC study on medicare margins of home health agencies.

Subtitle B—Direct Graduate Medical Education

- Sec. 611. Extension of update limitation on high cost programs.
- Sec. 612. Redistribution of unused resident positions.

Subtitle C—Other Provisions

- Sec. 621. Modifications to Medicare Payment Advisory Commission (MedPAC).
- Sec. 622. Demonstration project for disease management for certain medicare beneficiaries with diabetes.
- Sec. 623. Demonstration project for medical adult day care services.

TITLE VII—MEDICARE BENEFITS ADMINISTRATION

- Sec. 701. Establishment of Medicare Benefits Administration.

TITLE VIII—REGULATORY REDUCTION AND CONTRACTING REFORM

Subtitle A—Regulatory Reform

- Sec. 801. Construction; definition of supplier.
- Sec. 802. Issuance of regulations.
- Sec. 803. Compliance with changes in regulations and policies.

Sec. 804. Reports and studies relating to regulatory reform.

Subtitle B—Contracting Reform

Sec. 811. Increased flexibility in medicare administration.

Sec. 812. Requirements for information security for medicare administrative contractors.

Subtitle C—Education and Outreach

Sec. 821. Provider education and technical assistance.

Sec. 822. Small provider technical assistance demonstration program.

Sec. 823. Medicare provider ombudsman; medicare beneficiary ombudsman.

Sec. 824. Beneficiary outreach demonstration program.

Subtitle D—Appeals and Recovery

Sec. 831. Transfer of responsibility for medicare appeals.

Sec. 832. Process for expedited access to review.

Sec. 833. Revisions to medicare appeals process.

Sec. 834. Prepayment review.

Sec. 835. Recovery of overpayments.

Sec. 836. Provider enrollment process; right of appeal.

Sec. 837. Process for correction of minor errors and omissions on claims without pursuing appeals process.

Sec. 838. Prior determination process for certain items and services; advance beneficiary notices.

Subtitle E—Miscellaneous Provisions

Sec. 841. Policy development regarding evaluation and management (E & M) documentation guidelines.

Sec. 842. Improvement in oversight of technology and coverage.

Sec. 843. Treatment of hospitals for certain services under medicare secondary payor (MSP) provisions.

Sec. 844. EMTALA improvements.

Sec. 845. Emergency Medical Treatment and Active Labor Act (EMTALA) Technical Advisory Group.

Sec. 846. Authorizing use of arrangements with other hospice programs to provide core hospice services in certain circumstances.

Sec. 847. Application of OSHA bloodborne pathogens standard to certain hospitals.

Sec. 848. BIPA-related technical amendments and corrections.

Sec. 849. Conforming authority to waive a program exclusion.

Sec. 850. Treatment of certain dental claims.

Sec. 851. Annual publication of list of national coverage determinations.

TITLE IX—MEDICAID, PUBLIC HEALTH, AND OTHER HEALTH PROVISIONS

Subtitle A—Medicaid Provisions

Sec. 901. National Bipartisan Commission on the Future of Medicaid.

Sec. 902. GAO study on medicaid drug payment system.

Subtitle B—Internet Pharmacies

Sec. 911. Findings.

Sec. 912. Amendment to Federal Food, Drug, and Cosmetic Act.

Sec. 913. Public education.

Sec. 914. Study regarding coordination of regulatory activities.

Sec. 915. Effective date.

Subtitle C—Promotion of Electronic Prescription

Sec. 921. Program of grants to health care providers to implement electronic prescription drug programs.

Subtitle D—Treatment of Rare Diseases

Sec. 931. NIH Office of Rare Diseases at National Institutes of Health.

Sec. 932. Rare disease regional centers of excellence.

Subtitle E—Other Provisions Relating to Drugs

Sec. 941. GAO study regarding direct-to-consumer advertising of prescription drugs.

Sec. 942. Certain health professions programs regarding practice of pharmacy.

“SUBPART 3—PHARMACIST WORKFORCE PROGRAMS

“Sec. 771. Public service announcements.

“Sec. 772. Demonstration project.

“Sec. 773. Information technology.

“Sec. 774. Authorization of appropriations.

TITLE X—HEALTH-CARE RELATED TAX PROVISIONS

Sec. 1001. Eligibility for Archer MSA’s extended to account holders of Medicare+Choice MSA’s.

Sec. 1002. Adjustment of employer contributions to Combined Benefit Fund to reflect medicare prescription drug subsidy payments.

Sec. 1003. Expansion of human clinical trials qualifying for orphan drug credit.

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

SEC. 101. ESTABLISHMENT OF A MEDICARE PRESCRIPTION DRUG BENEFIT.

(a) IN GENERAL.—Title XVIII is amended—

(1) by redesignating part D as part E; and

(2) by inserting after part C the following new part:

“PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT
PROGRAM

“SEC. 1860A. BENEFITS; ELIGIBILITY; ENROLLMENT; AND COVERAGE PERIOD.

“(a) PROVISION OF QUALIFIED PRESCRIPTION DRUG COVERAGE THROUGH ENROLLMENT IN PLANS.—Subject to the succeeding provisions of this part, each individual who is entitled to benefits under part A or is enrolled under part B is entitled to obtain qualified prescription drug coverage (described in section 1860B(a)) as follows:

“(1) MEDICARE+CHOICE PLAN.—If the individual is eligible to enroll in a Medicare+Choice plan that provides qualified prescription drug coverage under section 1851(j),

the individual may enroll in the plan and obtain coverage through such plan.

“(2) PRESCRIPTION DRUG PLAN.—If the individual is not enrolled in a Medicare+Choice plan that provides qualified prescription drug coverage, the individual may enroll under this part in a prescription drug plan (as defined in section 1860J(a)(5)).

Such individuals shall have a choice of such plans under section 1860E(d).

“(b) GENERAL ELECTION PROCEDURES.—

“(1) IN GENERAL.—An individual eligible to make an election under subsection (a) may elect to enroll in a prescription drug plan under this part, or elect the option of qualified prescription drug coverage under a Medicare+Choice plan under part C, and to change such election only in such manner and form as may be prescribed by regulations of the Administrator of the Medicare Benefits Administration (appointed under section 1808(b)) (in this part referred to as the ‘Medicare Benefits Administrator’) and only during an election period prescribed in or under this subsection.

“(2) ELECTION PERIODS.—

“(A) IN GENERAL.—Except as provided in this paragraph, the election periods under this subsection shall be the same as the coverage election periods under the Medicare+Choice program under section 1851(e), including—

“(i) annual coordinated election periods; and

“(ii) special election periods.

In applying the last sentence of section 1851(e)(4) (relating to discontinuance of a Medicare+Choice election during the first year of eligibility) under this subparagraph, in the case of an election described in such section in which the individual had elected or is provided qualified prescription drug coverage at the time of such first enrollment, the individual shall be permitted to enroll in a prescription drug plan under this part at the

time of the election of coverage under the original fee-for-service plan.

“(B) INITIAL ELECTION PERIODS.—

“(i) INDIVIDUALS CURRENTLY COVERED.—In the case of an individual who is entitled to benefits under part A or enrolled under part B as of November 1, 2004, there shall be an initial election period of 6 months beginning on that date.

“(ii) INDIVIDUAL COVERED IN FUTURE.—In the case of an individual who is first entitled to benefits under part A or enrolled under part B after such date, there shall be an initial election period which is the same as the initial enrollment period under section 1837(d).

“(C) ADDITIONAL SPECIAL ELECTION PERIODS.—The Administrator shall establish special election periods—

“(i) in cases of individuals who have and involuntarily lose prescription drug coverage described in subsection (c)(2)(C);

“(ii) in cases described in section 1837(h) (relating to errors in enrollment), in the same manner as such section applies to part B;

“(iii) in the case of an individual who meets such exceptional conditions (including conditions provided under section 1851(e)(4)(D)) as the Administrator may provide; and

“(iv) in cases of individuals (as determined by the Administrator) who become eligible for prescription drug assistance under title XIX under section 1935(d).

“(c) GUARANTEED ISSUE; COMMUNITY RATING; AND NONDISCRIMINATION.—

“(1) GUARANTEED ISSUE.—

“(A) IN GENERAL.—An eligible individual who is eligible to elect qualified prescription drug coverage under a prescription drug plan or Medicare+Choice

1 plan at a time during which elections are accepted
 2 under this part with respect to the plan shall not be
 3 denied enrollment based on any health status-related
 4 factor (described in section 2702(a)(1) of the Public
 5 Health Service Act) or any other factor.

6 “(B) MEDICARE+CHOICE LIMITATIONS PER-
 7 MITTED.—The provisions of paragraphs (2) and (3)
 8 (other than subparagraph (C)(i), relating to default en-
 9 rollment) of section 1851(g) (relating to priority and
 10 limitation on termination of election) shall apply to
 11 PDP sponsors under this subsection.

12 “(2) COMMUNITY-RATED PREMIUM.—

13 “(A) IN GENERAL.—In the case of an individual
 14 who maintains (as determined under subparagraph (C))
 15 continuous prescription drug coverage since the date
 16 the individual first qualifies to elect prescription drug
 17 coverage under this part, a PDP sponsor or
 18 Medicare+Choice organization offering a prescription
 19 drug plan or Medicare+Choice plan that provides
 20 qualified prescription drug coverage and in which the
 21 individual is enrolled may not deny, limit, or condition
 22 the coverage or provision of covered prescription drug
 23 benefits or increase the premium under the plan based
 24 on any health status-related factor described in section
 25 2702(a)(1) of the Public Health Service Act or any
 26 other factor.

27 “(B) LATE ENROLLMENT PENALTY.—In the case
 28 of an individual who does not maintain such continuous
 29 prescription drug coverage (as described in subpara-
 30 graph (C)), a PDP sponsor or Medicare+Choice orga-
 31 nization may (notwithstanding any provision in this
 32 title) adjust the premium otherwise applicable or im-
 33 pose a pre-existing condition exclusion with respect to
 34 qualified prescription drug coverage in a manner that
 35 reflects additional actuarial risk involved. Such a risk
 36 shall be established through an appropriate actuarial

1 opinion of the type described in subparagraphs (A)
 2 through (C) of section 2103(c)(4).

3 “(C) CONTINUOUS PRESCRIPTION DRUG COV-
 4 ERAGE.—An individual is considered for purposes of
 5 this part to be maintaining continuous prescription
 6 drug coverage on and after the date the individual first
 7 qualifies to elect prescription drug coverage under this
 8 part if the individual establishes that as of such date
 9 the individual is covered under any of the following pre-
 10 scription drug coverage and before the date that is the
 11 last day of the 63-day period that begins on the date
 12 of termination of the particular prescription drug cov-
 13 erage involved (regardless of whether the individual
 14 subsequently obtains any of the following prescription
 15 drug coverage):

16 “(i) COVERAGE UNDER PRESCRIPTION DRUG
 17 PLAN OR MEDICARE+CHOICE PLAN.—Qualified
 18 prescription drug coverage under a prescription
 19 drug plan or under a Medicare+Choice plan.

20 “(ii) MEDICAID PRESCRIPTION DRUG COV-
 21 ERAGE.—Prescription drug coverage under a med-
 22 icaid plan under title XIX, including through the
 23 Program of All-inclusive Care for the Elderly
 24 (PACE) under section 1934, through a social
 25 health maintenance organization (referred to in
 26 section 4104(c) of the Balanced Budget Act of
 27 1997), or through a Medicare+Choice project that
 28 demonstrates the application of capitation payment
 29 rates for frail elderly medicare beneficiaries
 30 through the use of a interdisciplinary team and
 31 through the provision of primary care services to
 32 such beneficiaries by means of such a team at the
 33 nursing facility involved.

34 “(iii) PRESCRIPTION DRUG COVERAGE UNDER
 35 GROUP HEALTH PLAN.—Any outpatient prescrip-
 36 tion drug coverage under a group health plan, in-
 37 cluding a health benefits plan under the Federal

1 Employees Health Benefit Plan under chapter 89
 2 of title 5, United States Code, and a qualified re-
 3 tiree prescription drug plan as defined in section
 4 1860H(f)(1), but only if (subject to subparagraph
 5 (E)(ii)) the coverage provides benefits at least
 6 equivalent to the benefits under a qualified pre-
 7 scription drug plan.

8 “(iv) PRESCRIPTION DRUG COVERAGE UNDER
 9 CERTAIN MEDIGAP POLICIES.—Coverage under a
 10 medicare supplemental policy under section 1882
 11 that provides benefits for prescription drugs
 12 (whether or not such coverage conforms to the
 13 standards for packages of benefits under section
 14 1882(p)(1)), but only if the policy was in effect on
 15 January 1, 2005, and if (subject to subparagraph
 16 (E)(ii)) the coverage provides benefits at least
 17 equivalent to the benefits under a qualified pre-
 18 scription drug plan.

19 “(v) STATE PHARMACEUTICAL ASSISTANCE
 20 PROGRAM.—Coverage of prescription drugs under a
 21 State pharmaceutical assistance program, but only
 22 if (subject to subparagraph (E)(ii)) the coverage
 23 provides benefits at least equivalent to the benefits
 24 under a qualified prescription drug plan.

25 “(vi) VETERANS’ COVERAGE OF PRESCRIPTION
 26 DRUGS.—Coverage of prescription drugs for vet-
 27 erans under chapter 17 of title 38, United States
 28 Code, but only if (subject to subparagraph (E)(ii))
 29 the coverage provides benefits at least equivalent to
 30 the benefits under a qualified prescription drug
 31 plan.

32 “(D) CERTIFICATION.—For purposes of carrying
 33 out this paragraph, the certifications of the type de-
 34 scribed in sections 2701(e) of the Public Health Service
 35 Act and in section 9801(e) of the Internal Revenue
 36 Code shall also include a statement for the period of

1 coverage of whether the individual involved had pre-
 2 scription drug coverage described in subparagraph (C).

3 “(E) DISCLOSURE.—

4 “(i) IN GENERAL.—Each entity that offers
 5 coverage of the type described in clause (iii), (iv),
 6 (v), or (vi) of subparagraph (C) shall provide for
 7 disclosure, consistent with standards established by
 8 the Administrator, of whether such coverage pro-
 9 vides benefits at least equivalent to the benefits
 10 under a qualified prescription drug plan.

11 “(ii) WAIVER OF LIMITATIONS.—An individual
 12 may apply to the Administrator to waive the re-
 13 quirement that coverage of such type provide bene-
 14 fits at least equivalent to the benefits under a
 15 qualified prescription drug plan, if the individual
 16 establishes that the individual was not adequately
 17 informed that such coverage did not provide such
 18 level of benefits.

19 “(F) CONSTRUCTION.—Nothing in this section
 20 shall be construed as preventing the disenrollment of
 21 an individual from a prescription drug plan or a
 22 Medicare+Choice plan based on the termination of an
 23 election described in section 1851(g)(3), including for
 24 non-payment of premiums or for other reasons speci-
 25 fied in subsection (d)(3), which takes into account a
 26 grace period described in section 1851(g)(3)(B)(i).

27 “(3) NONDISCRIMINATION.—A PDP sponsor offering
 28 a prescription drug plan shall not establish a service area
 29 in a manner that would discriminate based on health or
 30 economic status of potential enrollees.

31 “(d) EFFECTIVE DATE OF ELECTIONS.—

32 “(1) IN GENERAL.—Except as provided in this section,
 33 the Administrator shall provide that elections under sub-
 34 section (b) take effect at the same time as the Adminis-
 35 trator provides that similar elections under section 1851(e)
 36 take effect under section 1851(f).

“(2) NO ELECTION EFFECTIVE BEFORE 2005.—In no case shall any election take effect before January 1, 2005.

“(3) TERMINATION.—The Administrator shall provide for the termination of an election in the case of—

“(A) termination of coverage under both part A and part B; and

“(B) termination of elections described in section 1851(g)(3) (including failure to pay required premiums).

“SEC. 1860B. REQUIREMENTS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE.

“(a) REQUIREMENTS.—

“(1) IN GENERAL.—For purposes of this part and part C, the term ‘qualified prescription drug coverage’ means either of the following:

“(A) STANDARD COVERAGE WITH ACCESS TO NEGOTIATED PRICES.—Standard coverage (as defined in subsection (b)) and access to negotiated prices under subsection (d).

“(B) ACTUARIALLY EQUIVALENT COVERAGE WITH ACCESS TO NEGOTIATED PRICES.—Coverage of covered outpatient drugs which meets the alternative coverage requirements of subsection (c) and access to negotiated prices under subsection (d), but only if it is approved by the Administrator, as provided under subsection (c).

“(2) PERMITTING ADDITIONAL OUTPATIENT PRESCRIPTION DRUG COVERAGE.—

“(A) IN GENERAL.—Subject to subparagraph (B), nothing in this part shall be construed as preventing qualified prescription drug coverage from including coverage of covered outpatient drugs that exceeds the coverage required under paragraph (1), but any such additional coverage shall be limited to coverage of covered outpatient drugs.

“(B) DISAPPROVAL AUTHORITY.—The Administrator shall review the offering of qualified prescription drug coverage under this part or part C. If the Admin-

1 istrator finds that, in the case of a qualified prescrip-
 2 tion drug coverage under a prescription drug plan or
 3 a Medicare+Choice plan, that the organization or spon-
 4 sor offering the coverage is engaged in activities in-
 5 tended to discourage enrollment of classes of eligible
 6 medicare beneficiaries obtaining coverage through the
 7 plan on the basis of their higher likelihood of utilizing
 8 prescription drug coverage, the Administrator may ter-
 9 minate the contract with the sponsor or organization
 10 under this part or part C.

11 “(3) APPLICATION OF SECONDARY PAYOR PROVI-
 12 SIONS.—The provisions of section 1852(a)(4) shall apply
 13 under this part in the same manner as they apply under
 14 part C.

15 “(b) STANDARD COVERAGE.—For purposes of this part,
 16 the ‘standard coverage’ is coverage of covered outpatient drugs
 17 (as defined in subsection (f)) that meets the following require-
 18 ments:

19 “(1) DEDUCTIBLE.—The coverage has an annual
 20 deductible—

21 “(A) for 2005, that is equal to \$250; or

22 “(B) for a subsequent year, that is equal to the
 23 amount specified under this paragraph for the previous
 24 year increased by the percentage specified in paragraph
 25 (5) for the year involved.

26 Any amount determined under subparagraph (B) that is
 27 not a multiple of \$10 shall be rounded to the nearest mul-
 28 tiple of \$10.

29 “(2) LIMITS ON COST-SHARING.—

30 “(A) IN GENERAL.—The coverage has cost-sharing
 31 (for costs above the annual deductible specified in para-
 32 graph (1) and up to the initial coverage limit under
 33 paragraph (3)) as follows:

34 “(i) FIRST COPAYMENT RANGE.—For costs
 35 above the annual deductible specified in paragraph
 36 (1) and up to amount specified in subparagraph
 37 (C), the cost-sharing—

1 “(I) is equal to 20 percent; or

2 “(II) is actuarially equivalent (using proc-
3 esses established under subsection (e)) to an
4 average expected payment of 20 percent of
5 such costs.

6 “(ii) SECONDARY COPAYMENT RANGE.—For
7 costs above the amount specified in subparagraph
8 (C) and up to the initial coverage limit, the cost-
9 sharing—

10 “(I) is equal to 50 percent; or

11 “(II) is actuarially consistent (using proc-
12 esses established under subsection (e)) with an
13 average expected payment of 50 percent of
14 such costs.

15 “(B) USE OF TIERED COPAYMENTS.—Nothing in
16 this part shall be construed as preventing a PDP spon-
17 sor from applying tiered copayments, so long as such
18 tiered copayments are consistent with subparagraph
19 (A).

20 “(C) INITIAL COPAYMENT THRESHOLD.—The
21 amount specified in this subparagraph—

22 “(i) for 2005, is equal to \$1,000; or

23 “(ii) for a subsequent year, is equal to the
24 amount specified in this subparagraph for the pre-
25 vious year, increased by the annual percentage in-
26 crease described in paragraph (5) for the year in-
27 volved.

28 Any amount determined under clause (ii) that is not a
29 multiple of \$10 shall be rounded to the nearest mul-
30 tiple of \$10.

31 “(3) INITIAL COVERAGE LIMIT.—Subject to paragraph
32 (4), the coverage has an initial coverage limit on the max-
33 imum costs that may be recognized for payment purposes
34 (above the annual deductible)—

35 “(A) for 2005, that is equal to \$2,000; or

36 “(B) for a subsequent year, that is equal to the
37 amount specified in this paragraph for the previous

1 year, increased by the annual percentage increase de-
 2 scribed in paragraph (5) for the year involved.

3 Any amount determined under subparagraph (B) that is
 4 not a multiple of \$25 shall be rounded to the nearest mul-
 5 tiple of \$25.

6 “(4) CATASTROPHIC PROTECTION.—

7 “(A) IN GENERAL.—Notwithstanding paragraph
 8 (3), the coverage provides benefits with no cost-sharing
 9 after the individual has incurred costs (as described in
 10 subparagraph (C)) for covered outpatient drugs in a
 11 year equal to the annual out-of-pocket threshold speci-
 12 fied in subparagraph (B).

13 “(B) ANNUAL OUT-OF-POCKET THRESHOLD.—For
 14 purposes of this part, the ‘annual out-of-pocket thresh-
 15 old’ specified in this subparagraph—

16 “(i) for 2005, is equal to \$4,500; or

17 “(ii) for a subsequent year, is equal to the
 18 amount specified in this subparagraph for the pre-
 19 vious year, increased by the annual percentage in-
 20 crease described in paragraph (5) for the year in-
 21 volved.

22 Any amount determined under clause (ii) that is not a
 23 multiple of \$100 shall be rounded to the nearest mul-
 24 tiple of \$100.

25 “(C) APPLICATION.—In applying subparagraph
 26 (A)—

27 “(i) incurred costs shall only include costs in-
 28 curred for the annual deductible (described in para-
 29 graph (1)), cost-sharing (described in paragraph
 30 (2)), and amounts for which benefits are not pro-
 31 vided because of the application of the initial cov-
 32 erage limit described in paragraph (3); and

33 “(ii) such costs shall be treated as incurred
 34 only if they are paid by the individual, under sec-
 35 tion 1860G, or under title XIX and the individual
 36 is not reimbursed (through insurance or otherwise)
 37 by another person for such costs.

“(5) ANNUAL PERCENTAGE INCREASE.—For purposes of this part, the annual percentage increase specified in this paragraph for a year is equal to the annual percentage increase in average per capita aggregate expenditures for covered outpatient drugs in the United States for medicare beneficiaries, as determined by the Administrator for the 12-month period ending in July of the previous year.

“(c) ALTERNATIVE COVERAGE REQUIREMENTS.—A prescription drug plan or Medicare+Choice plan may provide a different prescription drug benefit design from the standard coverage described in subsection (b) so long as the following requirements are met and the plan applies for, and receives, the approval of the Administrator for such benefit design:

“(1) ASSURING AT LEAST ACTUARIALLY EQUIVALENT COVERAGE.—

“(A) ASSURING EQUIVALENT VALUE OF TOTAL COVERAGE.—The actuarial value of the total coverage (as determined under subsection (e)) is at least equal to the actuarial value (as so determined) of standard coverage.

“(B) ASSURING EQUIVALENT UNSUBSIDIZED VALUE OF COVERAGE.—The unsubsidized value of the coverage is at least equal to the unsubsidized value of standard coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage (as determined under subsection (e)) exceeds the actuarial value of the subsidy payments under section 1860H with respect to such coverage.

“(C) ASSURING STANDARD PAYMENT FOR COSTS AT INITIAL COVERAGE LIMIT.—The coverage is designed, based upon an actuarially representative pattern of utilization (as determined under subsection (e)), to provide for the payment, with respect to costs incurred that are equal to the initial coverage limit under subsection (b)(3), of an amount equal to at least the sum of the following products:

1 “(i) FIRST COPAYMENT RANGE.—The product
2 of—

3 “(I) the amount by which the initial co-
4 payment threshold described in subsection
5 (b)(2)(C) exceeds the deductible described in
6 subsection (b)(1); and

7 “(II) 100 percent minus the cost-sharing
8 percentage specified in subsection
9 (b)(2)(A)(i)(I).

10 “(ii) SECONDARY COPAYMENT RANGE.—The
11 product of—

12 “(I) the amount by which the initial cov-
13 erage limit described in subsection (b)(3) ex-
14 ceeds the initial copayment threshold described
15 in subsection (b)(2)(C); and

16 “(II) 100 percent minus the cost-sharing
17 percentage specified in subsection
18 (b)(2)(A)(ii)(I).

19 “(2) CATASTROPHIC PROTECTION.—The coverage pro-
20 vides for beneficiaries the catastrophic protection described
21 in subsection (b)(4).

22 “(d) ACCESS TO NEGOTIATED PRICES.—

23 “(1) IN GENERAL.—Under qualified prescription drug
24 coverage offered by a PDP sponsor or a Medicare+Choice
25 organization, the sponsor or organization shall provide
26 beneficiaries with access to negotiated prices (including ap-
27 plicable discounts) used for payment for covered outpatient
28 drugs, regardless of the fact that no benefits may be pay-
29 able under the coverage with respect to such drugs because
30 of the application of cost-sharing or an initial coverage
31 limit (described in subsection (b)(3)). Insofar as a State
32 elects to provide medical assistance under title XIX for a
33 drug based on the prices negotiated by a prescription drug
34 plan under this part, the requirements of section 1927 shall
35 not apply to such drugs.

36 “(2) DISCLOSURE.—The PDP sponsor or
37 Medicare+Choice organization shall disclose to the Admin-

1 istrator (in a manner specified by the Administrator) the
 2 extent to which discounts or rebates made available to the
 3 sponsor or organization by a manufacturer are passed
 4 through to enrollees through pharmacies and other dis-
 5 pensers or otherwise. The provisions of section
 6 1927(b)(3)(D) shall apply to information disclosed to the
 7 Administrator under this paragraph in the same manner as
 8 such provisions apply to information disclosed under such
 9 section.

10 “(e) ACTUARIAL VALUATION; DETERMINATION OF AN-
 11 NUAL PERCENTAGE INCREASES.—

12 “(1) PROCESSES.—For purposes of this section, the
 13 Administrator shall establish processes and methods—

14 “(A) for determining the actuarial valuation of
 15 prescription drug coverage, including—

16 “(i) an actuarial valuation of standard cov-
 17 erage and of the reinsurance subsidy payments
 18 under section 1860H;

19 “(ii) the use of generally accepted actuarial
 20 principles and methodologies; and

21 “(iii) applying the same methodology for de-
 22 terminations of alternative coverage under sub-
 23 section (c) as is used with respect to determina-
 24 tions of standard coverage under subsection (b);
 25 and

26 “(B) for determining annual percentage increases
 27 described in subsection (b)(5).

28 “(2) USE OF OUTSIDE ACTUARIES.—Under the proc-
 29 esses under paragraph (1)(A), PDP sponsors and
 30 Medicare+Choice organizations may use actuarial opinions
 31 certified by independent, qualified actuaries to establish ac-
 32 tuarial values.

33 “(f) COVERED OUTPATIENT DRUGS DEFINED.—

34 “(1) IN GENERAL.—Except as provided in this sub-
 35 section, for purposes of this part, the term ‘covered out-
 36 patient drug’ means—

“(A) a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i) or (A)(ii) of section 1927(k)(2); or

“(B) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section, and such term includes a vaccine licensed under section 351 of the Public Health Service Act and any use of a covered outpatient drug for a medically accepted indication (as defined in section 1927(k)(6)).

“(2) EXCLUSIONS.—

“(A) IN GENERAL.—Such term does not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2), other than subparagraph (E) thereof (relating to smoking cessation agents), or under section 1927(d)(3).

“(B) AVOIDANCE OF DUPLICATE COVERAGE.—A drug prescribed for an individual that would otherwise be a covered outpatient drug under this part shall not be so considered if payment for such drug is available under part A or B for an individual entitled to benefits under part A and enrolled under part B.

“(3) APPLICATION OF FORMULARY RESTRICTIONS.—A drug prescribed for an individual that would otherwise be a covered outpatient drug under this part shall not be so considered under a plan if the plan excludes the drug under a formulary and such exclusion is not successfully appealed under section 1860C(f)(2).

“(4) APPLICATION OF GENERAL EXCLUSION PROVISIONS.—A prescription drug plan or Medicare+Choice plan may exclude from qualified prescription drug coverage any covered outpatient drug—

“(A) for which payment would not be made if section 1862(a) applied to part D; or

“(B) which are not prescribed in accordance with the plan or this part.

Such exclusions are determinations subject to reconsideration and appeal pursuant to section 1860C(f).

“SEC. 1860C. BENEFICIARY PROTECTIONS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE.

“(a) GUARANTEED ISSUE, COMMUNITY-RELATED PREMIUMS, ACCESS TO NEGOTIATED PRICES, AND NONDISCRIMINATION.—For provisions requiring guaranteed issue, community-rated premiums, access to negotiated prices, and nondiscrimination, see sections 1860A(c)(1), 1860A(c)(2), 1860B(d), and 1860F(b), respectively.

“(b) DISSEMINATION OF INFORMATION.—

“(1) GENERAL INFORMATION.—A PDP sponsor shall disclose, in a clear, accurate, and standardized form to each enrollee with a prescription drug plan offered by the sponsor under this part at the time of enrollment and at least annually thereafter, the information described in section 1852(c)(1) relating to such plan. Such information includes the following:

“(A) Access to covered outpatient drugs, including access through pharmacy networks.

“(B) How any formulary used by the sponsor functions.

“(C) Co-payments and deductible requirements, including the identification of the tiered or other copayment level applicable to each drug (or class of drugs).

“(D) Grievance and appeals procedures.

“(2) DISCLOSURE UPON REQUEST OF GENERAL COVERAGE, UTILIZATION, AND GRIEVANCE INFORMATION.—Upon request of an individual eligible to enroll under a prescription drug plan, the PDP sponsor shall provide the information described in section 1852(c)(2) (other than subparagraph (D)) to such individual.

“(3) RESPONSE TO BENEFICIARY QUESTIONS.—Each PDP sponsor offering a prescription drug plan shall have a mechanism for providing specific information to enrollees upon request. The sponsor shall make available on a timely

basis, through an Internet website and in writing upon request, information on specific changes in its formulary.

“(4) CLAIMS INFORMATION.—Each PDP sponsor offering a prescription drug plan must furnish to enrolled individuals in a form easily understandable to such individuals an explanation of benefits (in accordance with section 1806(a) or in a comparable manner) and a notice of the benefits in relation to initial coverage limit and annual out-of-pocket threshold for the current year, whenever prescription drug benefits are provided under this part (except that such notice need not be provided more often than monthly).

“(c) ACCESS TO COVERED BENEFITS.—

“(1) ASSURING PHARMACY ACCESS.—

“(A) IN GENERAL.—The PDP sponsor of the prescription drug plan shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (as determined by the Administrator and including adequate emergency access) for enrolled beneficiaries, in accordance with standards established under section 1860D(e) that ensure such convenient access.

“(B) USE OF POINT-OF-SERVICE SYSTEM.—A PDP sponsor shall establish an optional point-of-service method of operation under which—

“(i) the plan provides access to any or all pharmacies that are not participating pharmacies in its network; and

“(ii) the plan may charge beneficiaries through adjustments in premiums and copayments any additional costs associated with the point-of-service option.

The additional copayments so charged shall not count toward the application of section 1860B(b).

“(2) USE OF STANDARDIZED TECHNOLOGY.—

“(A) IN GENERAL.—The PDP sponsor of a prescription drug plan shall issue (and reissue, as appro-

1 priate) such a card (or other technology) that may be
 2 used by an enrolled beneficiary to assure access to ne-
 3 gotiated prices under section 1860B(d) for the pur-
 4 chase of prescription drugs for which coverage is not
 5 otherwise provided under the prescription drug plan.

6 “(B) STANDARDS.—

7 “(i) DEVELOPMENT.—The Administrator shall
 8 provide for the development of national standards
 9 relating to a standardized format for the card or
 10 other technology referred to in subparagraph (A).
 11 Such standards shall be compatible with standards
 12 established under part C of title XI.

13 “(ii) APPLICATION OF ADVISORY TASK
 14 FORCE.—The advisory task force established under
 15 subsection (d)(3)(B)(ii) shall provide recommenda-
 16 tions to the Administrator under such subsection
 17 regarding the standards developed under clause (i).

18 “(3) REQUIREMENTS ON DEVELOPMENT AND APPLICA-
 19 TION OF FORMULARIES.—If a PDP sponsor of a prescrip-
 20 tion drug plan uses a formulary, the following requirements
 21 must be met:

22 “(A) PHARMACY AND THERAPEUTIC (P&T) COM-
 23 MITTEE.—The sponsor must establish a pharmacy and
 24 therapeutic committee that develops and reviews the
 25 formulary. Such committee shall include at least one
 26 physician and at least one pharmacist both with exper-
 27 tise in the care of elderly or disabled persons and a ma-
 28 jority of its members shall consist of individuals who
 29 are a physician or a pharmacist (or both).

30 “(B) FORMULARY DEVELOPMENT.—In developing
 31 and reviewing the formulary, the committee shall base
 32 clinical decisions on the strength of scientific evidence
 33 and standards of practice, including assessing peer-re-
 34 viewed medical literature, such as randomized clinical
 35 trials, pharmacoeconomic studies, outcomes research
 36 data, and such other information as the committee de-
 37 termines to be appropriate.

“(C) INCLUSION OF DRUGS IN ALL THERAPEUTIC CATEGORIES.—The formulary must include drugs within each therapeutic category and class of covered outpatient drugs (although not necessarily for all drugs within such categories and classes).

“(D) PROVIDER EDUCATION.—The committee shall establish policies and procedures to educate and inform health care providers concerning the formulary.

“(E) NOTICE BEFORE REMOVING DRUGS FROM FORMULARY.—Any removal of a drug from a formulary shall take effect only after appropriate notice is made available to beneficiaries and physicians.

“(F) GRIEVANCES AND APPEALS RELATING TO APPLICATION OF FORMULARIES.—For provisions relating to grievances and appeals of coverage, see subsections (e) and (f).

“(d) COST AND UTILIZATION MANAGEMENT; QUALITY ASSURANCE; MEDICATION THERAPY MANAGEMENT PROGRAM.—

“(1) IN GENERAL.—The PDP sponsor shall have in place with respect to covered outpatient drugs—

“(A) an effective cost and drug utilization management program, including medically appropriate incentives to use generic drugs and therapeutic interchange, when appropriate;

“(B) quality assurance measures and systems to reduce medical errors and adverse drug interactions, including a medication therapy management program described in paragraph (2) and for years beginning with 2006, an electronic prescription program described in paragraph (3); and

“(C) a program to control fraud, abuse, and waste.

Nothing in this section shall be construed as impairing a PDP sponsor from applying cost management tools (including differential payments) under all methods of operation.

“(2) MEDICATION THERAPY MANAGEMENT PROGRAM.—

“(A) IN GENERAL.—A medication therapy management program described in this paragraph is a program of drug therapy management and medication administration that is designed to assure, with respect to beneficiaries with chronic diseases (such as diabetes, asthma, hypertension, and congestive heart failure) or multiple prescriptions, that covered outpatient drugs under the prescription drug plan are appropriately used to achieve therapeutic goals and reduce the risk of adverse events, including adverse drug interactions.

“(B) ELEMENTS.—Such program may include—

“(i) enhanced beneficiary understanding of such appropriate use through beneficiary education, counseling, and other appropriate means;

“(ii) increased beneficiary adherence with prescription medication regimens through medication refill reminders, special packaging, and other appropriate means; and

“(iii) detection of patterns of overuse and underuse of prescription drugs.

“(C) DEVELOPMENT OF PROGRAM IN COOPERATION WITH LICENSED PHARMACISTS.—The program shall be developed in cooperation with licensed pharmacists and physicians.

“(D) CONSIDERATIONS IN PHARMACY FEES.—The PDP sponsor of a prescription drug program shall take into account, in establishing fees for pharmacists and others providing services under the medication therapy management program, the resources and time used in implementing the program.

“(3) ELECTRONIC PRESCRIPTION PROGRAM.—

“(A) IN GENERAL.—An electronic prescription drug program described in this paragraph is a program that includes at least the following components, consistent with national standards established under subparagraph (B):

“(i) ELECTRONIC TRANSMITTAL OF PRESCRIPTIONS.—Prescriptions are only received electronically, except in emergency cases and other exceptional circumstances recognized by the Administrator.

“(ii) PROVISION OF INFORMATION TO PRESCRIBING HEALTH CARE PROFESSIONAL.—The program provides, upon transmittal of a prescription by a prescribing health care professional, for transmittal by the pharmacist to the professional of information that includes—

“(I) information (to the extent available and feasible) on the drugs being prescribed for that patient and other information relating to the medical history or condition of the patient that may be relevant to the appropriate prescription for that patient;

“(II) cost-effective alternatives (if any) for the use of the drug prescribed; and

“(III) information on the drugs included in the applicable formulary.

To the extent feasible, such program shall permit the prescribing health care professional to provide (and be provided) related information on an interactive, real-time basis.

“(B) STANDARDS.—

“(i) DEVELOPMENT.—The Administrator shall provide for the development of national standards relating to the electronic prescription drug program described in subparagraph (A). Such standards shall be compatible with standards established under part C of title XI.

“(ii) ADVISORY TASK FORCE.—In developing such standards and the standards described in subsection (c)(2)(B)(i) the Administrator shall establish a task force that includes representatives of physicians, hospitals, pharmacists, and technology

experts and representatives of the Departments of Veterans Affairs and Defense and other appropriate Federal agencies to provide recommendations to the Administrator on such standards, including recommendations relating to the following:

“(I) The range of available computerized prescribing software and hardware and their costs to develop and implement.

“(II) The extent to which such systems reduce medication errors and can be readily implemented by physicians and hospitals.

“(III) Efforts to develop a common software platform for computerized prescribing.

“(IV) The cost of implementing such systems in the range of hospital and physician office settings, including hardware, software, and training costs.

“(V) Implementation issues as they relate to part C of title XI, and current Federal and State prescribing laws and regulations and their impact on implementation of computerized prescribing.

“(iii) DEADLINES.—

“(I) The Administrator shall constitute the task force under clause (ii) by not later than April 1, 2003.

“(II) Such task force shall submit recommendations to Administrator by not later than January 1, 2004.

“(III) The Administrator shall develop and promulgate the national standards referred to in clause (ii) by not later than July 1, 2004.

“(C) REFERENCE TO AVAILABILITY OF GRANT FUNDS.—Grant funds are authorized under section 3990 of the Public Health Service Act to provide assistance to health care providers in implementing electronic prescription drug programs.

“(4) TREATMENT OF ACCREDITATION.—Section 1852(e)(4) (relating to treatment of accreditation) shall apply to prescription drug plans under this part with respect to the following requirements, in the same manner as they apply to Medicare+Choice plans under part C with respect to the requirements described in a clause of section 1852(e)(4)(B):

“(A) Paragraph (1) (including quality assurance), including medication therapy management program under paragraph (2).

“(B) Subsection (c)(1) (relating to access to covered benefits).

“(C) Subsection (g) (relating to confidentiality and accuracy of enrollee records).

“(5) PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS.—Each PDP sponsor shall provide that each pharmacy or other dispenser that arranges for the dispensing of a covered outpatient drug shall inform the beneficiary at the time of purchase of the drug of any differential between the price of the prescribed drug to the enrollee and the price of the lowest cost generic drug covered under the plan that is therapeutically equivalent and bioequivalent.

“(e) GRIEVANCE MECHANISM, COVERAGE DETERMINATIONS, AND RECONSIDERATIONS.—

“(1) IN GENERAL.—Each PDP sponsor shall provide meaningful procedures for hearing and resolving grievances between the organization (including any entity or individual through which the sponsor provides covered benefits) and enrollees with prescription drug plans of the sponsor under this part in accordance with section 1852(f).

“(2) APPLICATION OF COVERAGE DETERMINATION AND RECONSIDERATION PROVISIONS.—A PDP sponsor shall meet the requirements of paragraphs (1) through (3) of section 1852(g) with respect to covered benefits under the prescription drug plan it offers under this part in the same manner as such requirements apply to a

1 Medicare+Choice organization with respect to benefits it
 2 offers under a Medicare+Choice plan under part C.

3 “(3) REQUEST FOR REVIEW OF TIERED FORMULARY
 4 DETERMINATIONS.—In the case of a prescription drug plan
 5 offered by a PDP sponsor that provides for tiered cost-
 6 sharing for drugs included within a formulary and provides
 7 lower cost-sharing for preferred drugs included within the
 8 formulary, an individual who is enrolled in the plan may re-
 9 quest coverage of a nonpreferred drug under the terms ap-
 10 plicable for preferred drugs if the prescribing physician de-
 11 termines that the preferred drug for treatment of the same
 12 condition is not as effective for the individual or has ad-
 13 verse effects for the individual.

14 “(f) APPEALS.—

15 “(1) IN GENERAL.—Subject to paragraph (2), a PDP
 16 sponsor shall meet the requirements of paragraphs (4) and
 17 (5) of section 1852(g) with respect to drugs not included
 18 on any formulary in the same manner as such requirements
 19 apply to a Medicare+Choice organization with respect to
 20 benefits it offers under a Medicare+Choice plan under part
 21 C.

22 “(2) FORMULARY DETERMINATIONS.—An individual
 23 who is enrolled in a prescription drug plan offered by a
 24 PDP sponsor may appeal to obtain coverage for a covered
 25 outpatient drug that is not on a formulary of the sponsor
 26 if the prescribing physician determines that the formulary
 27 drug for treatment of the same condition is not as effective
 28 for the individual or has adverse effects for the individual.

29 “(g) CONFIDENTIALITY AND ACCURACY OF ENROLLEE
 30 RECORDS.—A PDP sponsor shall meet the requirements of sec-
 31 tion 1852(h) with respect to enrollees under this part in the
 32 same manner as such requirements apply to a
 33 Medicare+Choice organization with respect to enrollees under
 34 part C.

**“SEC. 1860D. REQUIREMENTS FOR PRESCRIPTION DRUG
PLAN (PDP) SPONSORS; CONTRACTS; ESTAB-
LISHMENT OF STANDARDS.**

“(a) GENERAL REQUIREMENTS.—Each PDP sponsor of a prescription drug plan shall meet the following requirements:

“(1) LICENSURE.—Subject to subsection (c), the sponsor is organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan.

“(2) ASSUMPTION OF FINANCIAL RISK.—

“(A) IN GENERAL.—Subject to subparagraph (B) and section 1860E(d)(2), the entity assumes full financial risk on a prospective basis for qualified prescription drug coverage that it offers under a prescription drug plan and that is not covered under section 1860H.

“(B) REINSURANCE PERMITTED.—The entity may obtain insurance or make other arrangements for the cost of coverage provided to any enrolled member under this part.

“(3) SOLVENCY FOR UNLICENSED SPONSORS.—In the case of a sponsor that is not described in paragraph (1), the sponsor shall meet solvency standards established by the Administrator under subsection (d).

“(b) CONTRACT REQUIREMENTS.—

“(1) IN GENERAL.—The Administrator shall not permit the election under section 1860A of a prescription drug plan offered by a PDP sponsor under this part, and the sponsor shall not be eligible for payments under section 1860G or 1860H, unless the Administrator has entered into a contract under this subsection with the sponsor with respect to the offering of such plan. Such a contract with a sponsor may cover more than one prescription drug plan. Such contract shall provide that the sponsor agrees to comply with the applicable requirements and standards of this

part and the terms and conditions of payment as provided for in this part.

“(2) NEGOTIATION REGARDING TERMS AND CONDITIONS.—The Administrator shall have the same authority to negotiate the terms and conditions of prescription drug plans under this part as the Director of the Office of Personnel Management has with respect to health benefits plans under chapter 89 of title 5, United States Code. In negotiating the terms and conditions regarding premiums for which information is submitted under section 1860F(a)(2), the Administrator shall take into account the subsidy payments under section 1860H and the adjusted community rate (as defined in section 1854(f)(3)) for the benefits covered.

“(3) INCORPORATION OF CERTAIN MEDICARE+CHOICE CONTRACT REQUIREMENTS.—The following provisions of section 1857 shall apply, subject to subsection (c)(5), to contracts under this section in the same manner as they apply to contracts under section 1857(a):

“(A) MINIMUM ENROLLMENT.—Paragraphs (1) and (3) of section 1857(b).

“(B) CONTRACT PERIOD AND EFFECTIVENESS.—Paragraphs (1) through (3) and (5) of section 1857(c).

“(C) PROTECTIONS AGAINST FRAUD AND BENEFICIARY PROTECTIONS.—Section 1857(d).

“(D) ADDITIONAL CONTRACT TERMS.—Section 1857(e); except that in applying section 1857(e)(2) under this part—

“(i) such section shall be applied separately to costs relating to this part (from costs under part C);

“(ii) in no case shall the amount of the fee established under this subparagraph for a plan exceed 20 percent of the maximum amount of the fee that may be established under subparagraph (B) of such section; and

“(iii) no fees shall be applied under this subparagraph with respect to Medicare+Choice plans.

“(E) INTERMEDIATE SANCTIONS.—Section 1857(g).

“(F) PROCEDURES FOR TERMINATION.—Section 1857(h).

“(4) RULES OF APPLICATION FOR INTERMEDIATE SANCTIONS.—In applying paragraph (3)(E)—

“(A) the reference in section 1857(g)(1)(B) to section 1854 is deemed a reference to this part; and

“(B) the reference in section 1857(g)(1)(F) to section 1852(k)(2)(A)(ii) shall not be applied.

“(c) WAIVER OF CERTAIN REQUIREMENTS TO EXPAND CHOICE.—

“(1) IN GENERAL.—In the case of an entity that seeks to offer a prescription drug plan in a State, the Administrator shall waive the requirement of subsection (a)(1) that the entity be licensed in that State if the Administrator determines, based on the application and other evidence presented to the Administrator, that any of the grounds for approval of the application described in paragraph (2) has been met.

“(2) GROUNDS FOR APPROVAL.—The grounds for approval under this paragraph are the grounds for approval described in subparagraph (B), (C), and (D) of section 1855(a)(2), and also include the application by a State of any grounds other than those required under Federal law.

“(3) APPLICATION OF WAIVER PROCEDURES.—With respect to an application for a waiver (or a waiver granted) under this subsection, the provisions of subparagraphs (E), (F), and (G) of section 1855(a)(2) shall apply.

“(4) LICENSURE DOES NOT SUBSTITUTE FOR OR CONSTITUTE CERTIFICATION.—The fact that an entity is licensed in accordance with subsection (a)(1) does not deem the entity to meet other requirements imposed under this part for a PDP sponsor.

“(5) REFERENCES TO CERTAIN PROVISIONS.—For purposes of this subsection, in applying provisions of section 1855(a)(2) under this subsection to prescription drug plans and PDP sponsors—

“(A) any reference to a waiver application under section 1855 shall be treated as a reference to a waiver application under paragraph (1); and

“(B) any reference to solvency standards shall be treated as a reference to solvency standards established under subsection (d).

“(d) SOLVENCY STANDARDS FOR NON-LICENSED SPONSORS.—

“(1) ESTABLISHMENT.—The Administrator shall establish, by not later than October 1, 2003, financial solvency and capital adequacy standards that an entity that does not meet the requirements of subsection (a)(1) must meet to qualify as a PDP sponsor under this part.

“(2) COMPLIANCE WITH STANDARDS.—Each PDP sponsor that is not licensed by a State under subsection (a)(1) and for which a waiver application has been approved under subsection (c) shall meet solvency and capital adequacy standards established under paragraph (1). The Administrator shall establish certification procedures for such PDP sponsors with respect to such solvency standards in the manner described in section 1855(c)(2).

“(e) OTHER STANDARDS.—The Administrator shall establish by regulation other standards (not described in subsection (d)) for PDP sponsors and plans consistent with, and to carry out, this part. The Administrator shall publish such regulations by October 1, 2003.

“(f) RELATION TO STATE LAWS.—

“(1) IN GENERAL.—The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency, except as provided in subsection (d)) with respect to prescription drug plans which are offered by PDP sponsors under this part.

1 “(2) PROHIBITION OF STATE IMPOSITION OF PREMIUM
2 TAXES.—No State may impose a premium tax or similar
3 tax with respect to premiums paid to PDP sponsors for
4 prescription drug plans under this part, or with respect to
5 any payments made to such a sponsor by the Administrator
6 under this part.

7 **“SEC. 1860E. PROCESS FOR BENEFICIARIES TO SELECT**
8 **QUALIFIED PRESCRIPTION DRUG COV-**
9 **ERAGE.**

10 “(a) IN GENERAL.—The Administrator shall establish a
11 process for the selection of the prescription drug plan or
12 Medicare+Choice plan which offer qualified prescription drug
13 coverage through which eligible individuals elect qualified pre-
14 scription drug coverage under this part.

15 “(b) ELEMENTS.—Such process shall include the fol-
16 lowing:

17 “(1) Annual, coordinated election periods, in which
18 such individuals can change the qualifying plans through
19 which they obtain coverage, in accordance with section
20 1860A(b)(2).

21 “(2) Active dissemination of information to promote
22 an informed selection among qualifying plans based upon
23 price, quality, and other features, in the manner described
24 in (and in coordination with) section 1851(d), including the
25 provision of annual comparative information, maintenance
26 of a toll-free hotline, and the use of non-Federal entities.

27 “(3) Coordination of elections through filing with a
28 Medicare+Choice organization or a PDP sponsor, in the
29 manner described in (and in coordination with) section
30 1851(c)(2).

31 “(c) MEDICARE+CHOICE ENROLLEE IN PLAN OFFERING
32 PRESCRIPTION DRUG COVERAGE MAY ONLY OBTAIN BENE-
33 FITS THROUGH THE PLAN.—An individual who is enrolled
34 under a Medicare+Choice plan that offers qualified prescrip-
35 tion drug coverage may only elect to receive qualified prescrip-
36 tion drug coverage under this part through such plan.

1 “(d) ASSURING ACCESS TO A CHOICE OF QUALIFIED PRE-
2SCRIPTION DRUG COVERAGE.—

3 “(1) CHOICE OF AT LEAST TWO PLANS IN EACH
4 AREA.—

5 “(A) IN GENERAL.—The Administrator shall as-
6sure that each individual who is entitled to benefits
7under part A or enrolled under part B and who is re-
8siding in an area in the United States has available,
9consistent with subparagraph (B), a choice of enroll-
10ment in at least two qualifying plans (as defined in
11paragraph (5)) in the area in which the individual re-
12sides, at least one of which is a prescription drug plan.

13 “(B) REQUIREMENT FOR DIFFERENT PLAN SPON-
14SORS.—The requirement in subparagraph (A) is not
15satisfied with respect to an area if only one PDP spon-
16sor or Medicare+Choice organization offers all the
17qualifying plans in the area.

18 “(2) GUARANTEEING ACCESS TO COVERAGE.—In order
19to assure access under paragraph (1) and consistent with
20paragraph (3), the Administrator may provide financial in-
21centives (including partial underwriting of risk) for a PDP
22sponsor to expand the service area under an existing pre-
23scription drug plan to adjoining or additional areas or to
24establish such a plan (including offering such a plan on a
25regional or nationwide basis), but only so long as (and to
26the extent) necessary to assure the access guaranteed
27under paragraph (1).

28 “(3) LIMITATION ON AUTHORITY.—In exercising au-
29thority under this subsection, the Administrator—

30 “(A) shall not provide for the full underwriting of
31financial risk for any PDP sponsor;

32 “(B) shall not provide for any underwriting of fi-
33nancial risk for a public PDP sponsor with respect to
34the offering of a nationwide prescription drug plan; and

35 “(C) shall seek to maximize the assumption of fi-
36nancial risk by PDP sponsors or Medicare+Choice or-
37ganizations.

“(4) REPORTS.—The Administrator shall, in each annual report to Congress under section 1808(f), include information on the exercise of authority under this subsection. The Administrator also shall include such recommendations as may be appropriate to minimize the exercise of such authority, including minimizing the assumption of financial risk.

“(5) QUALIFYING PLAN DEFINED.—For purposes of this subsection, the term ‘qualifying plan’ means a prescription drug plan or a Medicare+Choice plan that includes qualified prescription drug coverage.

“SEC. 1860F. SUBMISSION OF BIDS.

“(a) SUBMISSION OF BIDS AND RELATED INFORMATION.—

“(1) IN GENERAL.—Each PDP sponsor shall submit to the Administrator information of the type described in paragraph (2) in the same manner as information is submitted by a Medicare+Choice organization under section 1854(a)(1).

“(2) TYPE OF INFORMATION.—The information described in this paragraph is the following:

“(A) Information on the qualified prescription drug coverage to be provided.

“(B) Information on the actuarial value of the coverage.

“(C) Information on the bid for the coverage, including an actuarial certification of—

“(i) the actuarial basis for such bid;

“(ii) the portion of such bid attributable to benefits in excess of standard coverage; and

“(iii) the reduction in such bid resulting from the subsidy payments provided under section 1860H.

“(D) Such other information as the Administrator may require to carry out this part.

1 “(3) REVIEW.—The Administrator shall review the in-
 2 formation filed under paragraph (2) for the purpose of con-
 3 ducting negotiations under section 1860D(b)(2).

4 “(b) UNIFORM BID.—

5 “(1) IN GENERAL.—The bid for a prescription drug
 6 plan under this section may not vary among individuals en-
 7 rolled in the plan in the same service area.

8 “(2) CONSTRUCTION.—Nothing in paragraph (1) shall
 9 be construed as preventing the imposition of a late enroll-
 10 ment penalty under section 1860A(c)(2)(B).

11 “(c) COLLECTION.—

12 “(1) USE OF ELECTRONIC FUNDS TRANSFER MECHA-
 13 NISM OR, AT BENEFICIARY’S OPTION, WITHHOLDING FROM
 14 SOCIAL SECURITY PAYMENT.—In accordance with regula-
 15 tions, a PDP sponsor may encourage that enrollees under
 16 a plan make payment of the premium established by the
 17 plan under this part through an electronic funds transfer
 18 mechanism, such as automatic charges of an account at a
 19 financial institution or a credit or debit card account, or,
 20 at the option of an enrollee, through withholding from ben-
 21 efit payments in the manner provided under section 1840
 22 with respect to monthly premiums under section 1839. All
 23 such amounts shall be credited to the Medicare Prescrip-
 24 tion Drug Trust Fund.

25 “(2) OFFSETTING.—Reductions in premiums for cov-
 26 erage under parts A and B as a result of a selection of a
 27 Medicare+Choice plan may be used to reduce the premium
 28 otherwise imposed under paragraph (1).

29 “(3) PAYMENT OF PLANS.—PDP plans shall receive
 30 payment based on bid amounts in the same manner as
 31 Medicare+Choice organizations receive payment based on
 32 bid amounts under section 1853(a)(1)(A)(ii) except that
 33 such payment shall be made from the Medicare Prescrip-
 34 tion Drug Trust Fund.

35 “(d) ACCEPTANCE OF BENCHMARK AMOUNT AS FULL
 36 PREMIUM FOR SUBSIDIZED LOW-INCOME INDIVIDUALS IF NO
 37 STANDARD (OR EQUIVALENT) COVERAGE IN AN AREA.—

“(1) IN GENERAL.—If there is no standard prescription drug coverage (as defined in paragraph (2)) offered in an area, in the case of an individual who is eligible for a premium subsidy under section 1860G and resides in the area, the PDP sponsor of any prescription drug plan offered in the area (and any Medicare+Choice organization that offers qualified prescription drug coverage in the area) shall accept the benchmark bid amount (under section 1860G(b)(2)) as payment in full for the premium charge for qualified prescription drug coverage.

“(2) STANDARD PRESCRIPTION DRUG COVERAGE DEFINED.—For purposes of this subsection, the term ‘standard prescription drug coverage’ means qualified prescription drug coverage that is standard coverage or that has an actuarial value equivalent to the actuarial value for standard coverage.

“SEC. 1860G. PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS.

“(a) INCOME-RELATED SUBSIDIES FOR INDIVIDUALS WITH INCOME BELOW 150 PERCENT OF FEDERAL POVERTY LEVEL.—

“(1) FULL PREMIUM SUBSIDY AND REDUCTION OF COST-SHARING FOR INDIVIDUALS WITH INCOME BELOW 150 PERCENT OF FEDERAL POVERTY LEVEL.—In the case of a subsidy eligible individual (as defined in paragraph (4)) who is determined to have income that does not exceed 150 percent of the Federal poverty level, the individual is entitled under this section—

“(A) to an income-related premium subsidy equal to 100 percent of the amount described in subsection (b)(1); and

“(B) subject to subsection (c), to the substitution for the beneficiary cost-sharing described in paragraphs (1) and (2) of section 1860B(b) (up to the initial coverage limit specified in paragraph (3) of such section) of amounts that do not exceed \$2 for a multiple source

or generic drug (as described in section 1927(k)(7)(A))
and \$5 for a non-preferred drug.

“(2) SLIDING SCALE PREMIUM SUBSIDY AND REDUC-
TION OF COST-SHARING FOR INDIVIDUALS WITH INCOME
ABOVE 150, BUT BELOW 175 PERCENT, OF FEDERAL POV-
ERTY LEVEL.—In the case of a subsidy eligible individual
who is determined to have income that exceeds 150 per-
cent, but does not exceed 175 percent, of the Federal pov-
erty level, the individual is entitled under this section to—

“(A) an income-related premium subsidy deter-
mined on a linear sliding scale ranging from 100 per-
cent of the amount described in subsection (b)(1) for
individuals with incomes at 150 percent of such level
to 0 percent of such amount for individuals with in-
comes at 175 percent of such level; and

“(B) subject to subsection (c), to the substitution
for the beneficiary cost-sharing described in paragraphs
(1) and (2) of section 1860B(b) (up to the initial cov-
erage limit specified in paragraph (3) of such section)
of amounts that do not exceed \$2 for a multiple source
or generic drug (as described in section 1927(k)(7)(A))
and \$5 for a non-preferred drug.

“(3) CONSTRUCTION.—Nothing in this section shall be
construed as preventing a PDP sponsor from reducing to
0 the cost-sharing otherwise applicable to generic drugs.

“(4) DETERMINATION OF ELIGIBILITY.—

“(A) SUBSIDY ELIGIBLE INDIVIDUAL DEFINED.—
For purposes of this section, subject to subparagraph
(D), the term ‘subsidy eligible individual’ means an in-
dividual who—

“(i) is eligible to elect, and has elected, to ob-
tain qualified prescription drug coverage under this
part;

“(ii) has income below 175 percent of the Fed-
eral poverty line; and

“(iii) meets the resources requirement de-
scribed in section 1905(p)(1)(C).

“(B) DETERMINATIONS.—The determination of whether an individual residing in a State is a subsidy eligible individual and the amount of such individual’s income shall be determined under the State medicaid plan for the State under section 1935(a). In the case of a State that does not operate such a medicaid plan (either under title XIX or under a statewide waiver granted under section 1115), such determination shall be made under arrangements made by the Administrator.

“(C) INCOME DETERMINATIONS.—For purposes of applying this section—

“(i) income shall be determined in the manner described in section 1905(p)(1)(B); and

“(ii) the term ‘Federal poverty line’ means the official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved.

“(D) TREATMENT OF TERRITORIAL RESIDENTS.—In the case of an individual who is not a resident of the 50 States or the District of Columbia, the individual is not eligible to be a subsidy eligible individual but may be eligible for financial assistance with prescription drug expenses under section 1935(e).

“(E) TREATMENT OF CONFORMING MEDIGAP POLICIES.—For purposes of this section, the term ‘qualified prescription drug coverage’ includes a medicare supplemental policy described in section 1860H(b)(4).

“(5) INDEXING DOLLAR AMOUNTS.—

“(A) FOR 2006.—The dollar amounts applied under paragraphs (1)(B) and (2)(B) for 2006 shall be the dollar amounts specified in such paragraph increased by the annual percentage increase described in section 1860B(b)(5) for 2006.

“(B) FOR SUBSEQUENT YEARS.—The dollar amounts applied under paragraphs (1)(B) and (2)(B) for a year after 2006 shall be the amounts (under this paragraph) applied under paragraph (1)(B) or (2)(B) for the preceding year increased by the annual percentage increase described in section 1860B(b)(5) (relating to growth in medicare prescription drug costs per beneficiary) for the year involved.

“(b) PREMIUM SUBSIDY AMOUNT.—

“(1) IN GENERAL.—The premium subsidy amount described in this subsection for an individual residing in an area is the benchmark bid amount (as defined in paragraph (2)) for qualified prescription drug coverage offered by the prescription drug plan or the Medicare+Choice plan in which the individual is enrolled.

“(2) BENCHMARK BID AMOUNT DEFINED.—For purposes of this subsection, the term ‘benchmark bid amount’ means, with respect to qualified prescription drug coverage offered under—

“(A) a prescription drug plan that—

“(i) provides standard coverage (or alternative prescription drug coverage the actuarial value is equivalent to that of standard coverage), the bid amount for enrollment under the plan under this part (determined without regard to any subsidy under this section or any late enrollment penalty under section 1860A(c)(2)(B)); or

“(ii) provides alternative prescription drug coverage the actuarial value of which is greater than that of standard coverage, the bid amount described in clause (i) multiplied by the ratio of (I) the actuarial value of standard coverage, to (II) the actuarial value of the alternative coverage; or

“(B) a Medicare+Choice plan, the portion of the bid amount that is attributable to statutory drug benefits (described in section 1853(a)(1)(A)(ii)(II)).

“(c) RULES IN APPLYING COST-SHARING SUBSIDIES.—

“(1) IN GENERAL.—In applying subsections (a)(1)(B) and (a)(2)(B), nothing in this part shall be construed as preventing a plan or provider from waiving or reducing the amount of cost-sharing otherwise applicable.

“(2) LIMITATION ON CHARGES.—In the case of an individual receiving cost-sharing subsidies under subsection (a)(1)(B) or (a)(2)(B), the PDP sponsor may not charge more than \$5 per prescription.

“(3) APPLICATION OF INDEXING RULES.—The provisions of subsection (a)(4) shall apply to the dollar amount specified in paragraph (2) in the same manner as they apply to the dollar amounts specified in subsections (a)(1)(B) and (a)(2)(B).

“(d) ADMINISTRATION OF SUBSIDY PROGRAM.—The Administrator shall provide a process whereby, in the case of an individual who is determined to be a subsidy eligible individual and who is enrolled in prescription drug plan or is enrolled in a Medicare+Choice plan under which qualified prescription drug coverage is provided—

“(1) the Administrator provides for a notification of the PDP sponsor or Medicare+Choice organization involved that the individual is eligible for a subsidy and the amount of the subsidy under subsection (a);

“(2) the sponsor or organization involved reduces the premiums or cost-sharing otherwise imposed by the amount of the applicable subsidy and submits to the Administrator information on the amount of such reduction; and

“(3) the Administrator periodically and on a timely basis reimburses the sponsor or organization for the amount of such reductions.

The reimbursement under paragraph (3) with respect to cost-sharing subsidies may be computed on a capitated basis, taking into account the actuarial value of the subsidies and with appropriate adjustments to reflect differences in the risks actually involved.

“(e) RELATION TO MEDICAID PROGRAM.—

“(1) IN GENERAL.—For provisions providing for eligibility determinations, and additional financing, under the medicaid program, see section 1935.

“(2) MEDICAID PROVIDING WRAP AROUND BENEFITS.—The coverage provided under this part is primary payor to benefits for prescribed drugs provided under the medicaid program under title XIX.

“(3) COORDINATION.—The Administrator shall develop and implement a plan for the coordination of prescription drug benefits under this part with the benefits provided under the medicaid program under title XIX, with particular attention to insuring coordination of payments and prevention of fraud and abuse. In developing and implementing such plan, the Administrator shall involve the Secretary, the States, the data processing industry, pharmacists, and pharmaceutical manufacturers, and other experts.

“SEC. 1860H. SUBSIDIES FOR ALL MEDICARE BENEFICIARIES FOR QUALIFIED PRESCRIPTION DRUG COVERAGE.

“(a) SUBSIDY PAYMENT.—In order to reduce premium levels applicable to qualified prescription drug coverage for all medicare beneficiaries, to reduce adverse selection among prescription drug plans and Medicare+Choice plans that provide qualified prescription drug coverage, and to promote the participation of PDP sponsors under this part, the Administrator shall provide in accordance with this section for payment to a qualifying entity (as defined in subsection (b)) of the following subsidies:

“(1) DIRECT SUBSIDY.—In the case of an individual enrolled in a prescription drug plan, Medicare+Choice plan, or qualified retiree prescription drug plan, a direct subsidy equal to a percentage (specified by the Administrator consistent with subsection (d)(2)) of an amount equal to the actuarial value of the standard drug coverage provided under the respective plan.

“(2) SUBSIDY THROUGH REINSURANCE.—The reinsurance payment amount (as defined in subsection (c)) for excess costs incurred in providing qualified prescription drug coverage—

“(A) for individuals enrolled with a prescription drug plan under this part;

“(B) for individuals enrolled with a Medicare+Choice plan that provides qualified prescription drug coverage under part C; and

“(C) for individuals who are enrolled in a qualified retiree prescription drug plan.

This section constitutes budget authority in advance of appropriations Acts and represents the obligation of the Administrator to provide for the payment of amounts provided under this section.

“(b) QUALIFYING ENTITY DEFINED.—For purposes of this section, the term ‘qualifying entity’ means any of the following that has entered into an agreement with the Administrator to provide the Administrator with such information as may be required to carry out this section:

“(1) A PDP sponsor offering a prescription drug plan under this part.

“(2) A Medicare+Choice organization that provides qualified prescription drug coverage under a Medicare+Choice plan under part C.

“(3) The sponsor of a qualified retiree prescription drug plan (as defined in subsection (f)).

“(c) REINSURANCE PAYMENT AMOUNT.—

“(1) IN GENERAL.—Subject to subsection (d)(2) and paragraph (4), the reinsurance payment amount under this subsection for a qualifying covered individual (as defined in subsection (g)(1)) for a coverage year (as defined in subsection (g)(2)) is equal to the sum of the following:

“(A) For the portion of the individual’s gross covered prescription drug costs (as defined in paragraph (3)) for the year that exceeds the initial copayment threshold specified in section 1860B(b)(2)(C), but does

not exceed the initial coverage limit specified in section 1860B(b)(3), an amount equal to 30 percent of the allowable costs (as defined in paragraph (2)) attributable to such gross covered prescription drug costs.

“(B) For the portion of the individual’s gross covered prescription drug costs for the year that exceeds the annual out-of-pocket threshold specified in 1860B(b)(4)(B), an amount equal to 80 percent of the allowable costs attributable to such gross covered prescription drug costs.

“(2) ALLOWABLE COSTS.—For purposes of this section, the term ‘allowable costs’ means, with respect to gross covered prescription drug costs under a plan described in subsection (b) offered by a qualifying entity, the part of such costs that are actually paid (net of average percentage rebates) under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were standard coverage.

“(3) GROSS COVERED PRESCRIPTION DRUG COSTS.—For purposes of this section, the term ‘gross covered prescription drug costs’ means, with respect to an enrollee with a qualifying entity under a plan described in subsection (b) during a coverage year, the costs incurred under the plan (including costs attributable to administrative costs) for covered prescription drugs dispensed during the year, including costs relating to the deductible, whether paid by the enrollee or under the plan, regardless of whether the coverage under the plan exceeds standard coverage and regardless of when the payment for such drugs is made.

“(4) INDEXING DOLLAR AMOUNTS.—

“(A) AMOUNTS FOR 2005.—The dollar amounts applied under paragraph (1) for 2005 shall be the dollar amounts specified in such paragraph.

“(B) FOR 2006.—The dollar amounts applied under paragraph (1) for 2006 shall be the dollar

1 amounts specified in such paragraph increased by the
 2 annual percentage increase described in section
 3 1860B(b)(5) for 2006.

4 “(C) FOR SUBSEQUENT YEARS.—The dollar
 5 amounts applied under paragraph (1) for a year after
 6 2006 shall be the amounts (under this paragraph) ap-
 7 plied under paragraph (1) for the preceding year in-
 8 creased by the annual percentage increase described in
 9 section 1860B(b)(5) (relating to growth in medicare
 10 prescription drug costs per beneficiary) for the year in-
 11 volved.

12 “(D) ROUNDING.—Any amount, determined under
 13 the preceding provisions of this paragraph for a year,
 14 which is not a multiple of \$10 shall be rounded to the
 15 nearest multiple of \$10.

16 “(d) ADJUSTMENT OF PAYMENTS.—

17 “(1) ESTIMATION OF PAYMENTS.—The Administrator
 18 shall estimate—

19 “(A) the total payments to be made (without re-
 20 gard to this subsection) during a year under this sec-
 21 tion; and

22 “(B) the total payments to be made by qualifying
 23 entities for standard coverage under plans described in
 24 subsection (b) during the year.

25 “(2) ADJUSTMENT.—The Administrator shall propor-
 26 tionally adjust the payments made under this section for a
 27 coverage year in such manner so that—

28 “(A) the total of the payments made for the year
 29 under this section is equal to 65 percent of the total
 30 payments described in paragraph (1)(B) during the
 31 year; and

32 “(B) the ratio of the total of the payments made
 33 for direct subsidies under subsection (a)(1) for the year
 34 to the total of the payments made for reinsurance sub-
 35 sidies for the year under subsection (a)(2) is equal to
 36 the ratio of 35 to 30.

“(3) RISK ADJUSTMENT.—To the extent the Administrator determines it appropriate to avoid risk selection, the payments made for direct subsidies under subsection (a)(1) are subject to adjustment based upon risk factors specified by the Administrator.

“(e) PAYMENT METHODS.—

“(1) IN GENERAL.—Payments under this section shall be based on such a method as the Administrator determines. The Administrator may establish a payment method by which interim payments of amounts under this section are made during a year based on the Administrator’s best estimate of amounts that will be payable after obtaining all of the information.

“(2) SOURCE OF PAYMENTS.—Payments under this section shall be made from the Medicare Prescription Drug Trust Fund.

“(f) QUALIFIED RETIREE PRESCRIPTION DRUG PLAN DEFINED.—

“(1) IN GENERAL.—For purposes of this section, the term ‘qualified retiree prescription drug plan’ means employment-based retiree health coverage (as defined in paragraph (3)(A)) if, with respect to an individual enrolled (or eligible to be enrolled) under this part who is covered under the plan, the following requirements are met:

“(A) ASSURANCE.—The sponsor of the plan shall annually attest, and provide such assurances as the Administrator may require, that the coverage meets or exceeds the requirements for qualified prescription drug coverage.

“(B) AUDITS.—The sponsor (and the plan) shall maintain, and afford the Administrator access to, such records as the Administrator may require for purposes of audits and other oversight activities necessary to ensure the adequacy of prescription drug coverage, and the accuracy of payments made.

“(C) PROVISION OF CERTIFICATION OF PRESCRIPTION DRUG COVERAGE.—The sponsor of the plan shall

provide for issuance of certifications of the type described in section 1860A(c)(2)(D).

“(2) LIMITATION ON BENEFIT ELIGIBILITY.—No payment shall be provided under this section with respect to an individual who is enrolled under a qualified retiree prescription drug plan unless the individual is—

“(A) enrolled under this part;

“(B) is covered under the plan; and

“(C) is eligible to obtain qualified prescription drug coverage under section 1860A but did not elect such coverage under this part (either through a prescription drug plan or through a Medicare+Choice plan).

“(3) DEFINITIONS.—As used in this section:

“(A) EMPLOYMENT-BASED RETIREE HEALTH COVERAGE.—The term ‘employment-based retiree health coverage’ means health insurance or other coverage of health care costs for individuals enrolled under this part (or for such individuals and their spouses and dependents) based on their status as former employees or labor union members.

“(B) SPONSOR.—The term ‘sponsor’ means a plan sponsor, as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974.

“(g) GENERAL DEFINITIONS.—For purposes of this section:

“(1) QUALIFYING COVERED INDIVIDUAL.—The term ‘qualifying covered individual’ means an individual who—

“(A) is enrolled with a prescription drug plan under this part;

“(B) is enrolled with a Medicare+Choice plan that provides qualified prescription drug coverage under part C; or

“(C) is enrolled for benefits under this title and is covered under a qualified retiree prescription drug plan.

“(2) COVERAGE YEAR.—The term ‘coverage year’ means a calendar year in which covered outpatient drugs

1 are dispensed if a claim for payment is made under the
 2 plan for such drugs, regardless of when the claim is paid.

3 **“SEC. 1860I. MEDICARE PRESCRIPTION DRUG TRUST**
 4 **FUND.**

5 “(a) IN GENERAL.—There is created on the books of the
 6 Treasury of the United States a trust fund to be known as the
 7 ‘Medicare Prescription Drug Trust Fund’ (in this section re-
 8 ferred to as the ‘Trust Fund’). The Trust Fund shall consist
 9 of such gifts and bequests as may be made as provided in sec-
 10 tion 201(i)(1), and such amounts as may be deposited in, or
 11 appropriated to, such fund as provided in this part. Except as
 12 otherwise provided in this section, the provisions of subsections
 13 (b) through (i) of section 1841 shall apply to the Trust Fund
 14 in the same manner as they apply to the Federal Supple-
 15 mentary Medical Insurance Trust Fund under such section.

16 “(b) PAYMENTS FROM TRUST FUND.—

17 “(1) IN GENERAL.—The Managing Trustee shall pay
 18 from time to time from the Trust Fund such amounts as
 19 the Administrator certifies are necessary to make—

20 “(A) payments under section 1860G (relating to
 21 low-income subsidy payments);

22 “(B) payments under section 1860H (relating to
 23 subsidy payments); and

24 “(C) payments with respect to administrative ex-
 25 penses under this part in accordance with section
 26 201(g).

27 “(2) TRANSFERS TO MEDICAID ACCOUNT FOR IN-
 28 CREASED ADMINISTRATIVE COSTS.—The Managing Trustee
 29 shall transfer from time to time from the Trust Fund to
 30 the Grants to States for Medicaid account amounts the Ad-
 31 ministrator certifies are attributable to increases in pay-
 32 ment resulting from the application of a higher Federal
 33 matching percentage under section 1935(b).

34 “(c) DEPOSITS INTO TRUST FUND.—

35 “(1) LOW-INCOME TRANSFER.—There is hereby trans-
 36 ferred to the Trust Fund, from amounts appropriated for
 37 Grants to States for Medicaid, amounts equivalent to the

1 aggregate amount of the reductions in payments under sec-
 2 tion 1903(a)(1) attributable to the application of section
 3 1935(c).

4 “(2) APPROPRIATIONS TO COVER GOVERNMENT CON-
 5 TRIBUTIONS.—There are authorized to be appropriated
 6 from time to time, out of any moneys in the Treasury not
 7 otherwise appropriated, to the Trust Fund, an amount
 8 equivalent to the amount of payments made from the Trust
 9 Fund under subsection (b), reduced by the amount trans-
 10 ferred to the Trust Fund under paragraph (1).

11 “(d) RELATION TO SOLVENCY REQUIREMENTS.—Any pro-
 12 vision of law that relates to the solvency of the Trust Fund
 13 under this part shall take into account the Trust Fund and
 14 amounts receivable by, or payable from, the Trust Fund.

15 **“SEC. 1860J. DEFINITIONS; TREATMENT OF REF-**
 16 **ERENCES TO PROVISIONS IN PART C.**

17 “(a) DEFINITIONS.—For purposes of this part:

18 “(1) COVERED OUTPATIENT DRUGS.—The term ‘cov-
 19 ered outpatient drugs’ is defined in section 1860B(f).

20 “(2) INITIAL COVERAGE LIMIT.—The term ‘initial cov-
 21 erage limit’ means such limit as established under section
 22 1860B(b)(3), or, in the case of coverage that is not stand-
 23 ard coverage, the comparable limit (if any) established
 24 under the coverage.

25 “(3) MEDICARE PRESCRIPTION DRUG TRUST FUND.—
 26 The term ‘Medicare Prescription Drug Trust Fund’ means
 27 the Trust Fund created under section 1860I(a).

28 “(4) PDP SPONSOR.—The term ‘PDP sponsor’ means
 29 an entity that is certified under this part as meeting the
 30 requirements and standards of this part for such a sponsor.

31 “(5) PRESCRIPTION DRUG PLAN.—The term ‘prescrip-
 32 tion drug plan’ means health benefits coverage that—

33 “(A) is offered under a policy, contract, or plan by
 34 a PDP sponsor pursuant to, and in accordance with, a
 35 contract between the Administrator and the sponsor
 36 under section 1860D(b);

1 “(B) provides qualified prescription drug coverage;
2 and

3 “(C) meets the applicable requirements of the sec-
4 tion 1860C for a prescription drug plan.

5 “(6) QUALIFIED PRESCRIPTION DRUG COVERAGE.—
6 The term ‘qualified prescription drug coverage’ is defined
7 in section 1860B(a).

8 “(7) STANDARD COVERAGE.—The term ‘standard cov-
9 erage’ is defined in section 1860B(b).

10 “(b) APPLICATION OF MEDICARE+CHOICE PROVISIONS
11 UNDER THIS PART.—For purposes of applying provisions of
12 part C under this part with respect to a prescription drug plan
13 and a PDP sponsor, unless otherwise provided in this part such
14 provisions shall be applied as if—

15 “(1) any reference to a Medicare+Choice plan in-
16 cluded a reference to a prescription drug plan;

17 “(2) any reference to a provider-sponsored organiza-
18 tion included a reference to a PDP sponsor;

19 “(3) any reference to a contract under section 1857
20 included a reference to a contract under section 1860D(b);
21 and

22 “(4) any reference to part C included a reference to
23 this part.”.

24 (b) ADDITIONAL CONFORMING CHANGES.—

25 (1) CONFORMING REFERENCES TO PREVIOUS PART
26 D.—Any reference in law (in effect before the date of the
27 enactment of this Act) to part D of title XVIII of the So-
28 cial Security Act is deemed a reference to part E of such
29 title (as in effect after such date).

30 (2) CONFORMING AMENDMENT PERMITTING WAIVER
31 OF COST-SHARING.—Section 1128B(b)(3) (42 U.S.C.
32 1320a-7b(b)(3)) is amended—

33 (A) by striking “and” at the end of subparagraph
34 (E);

35 (B) by striking the period at the end of subpara-
36 graph (F) and inserting “; and”; and

(C) by adding at the end the following new subparagraph:

“(G) the waiver or reduction of any cost-sharing imposed under part D of title XVIII.”.

(3) SUBMISSION OF LEGISLATIVE PROPOSAL.—Not later than 6 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the appropriate committees of Congress a legislative proposal providing for such technical and conforming amendments in the law as are required by the provisions of this subtitle.

(c) STUDY ON TRANSITIONING PART B PRESCRIPTION DRUG COVERAGE.—Not later than January 1, 2004, the Medicare Benefits Administrator shall submit a report to Congress that makes recommendations regarding methods for providing benefits under part D of title XVIII of the Social Security Act for outpatient prescription drugs for which benefits are provided under part B of such title.

SEC. 102. OFFERING OF QUALIFIED PRESCRIPTION DRUG COVERAGE UNDER THE MEDICARE+CHOICE PROGRAM.

(a) IN GENERAL.—Section 1851 (42 U.S.C. 1395w–21) is amended by adding at the end the following new subsection:

“(j) AVAILABILITY OF PRESCRIPTION DRUG BENEFITS.—

“(1) OFFER OF QUALIFIED PRESCRIPTION DRUG COVERAGE.—

“(A) IN GENERAL.—A Medicare+Choice organization may not offer prescription drug coverage (other than that required under parts A and B) to an enrollee under a Medicare+Choice plan unless such drug coverage is at least qualified prescription drug coverage and unless the requirements of this subsection with respect to such coverage are met.

“(B) CONSTRUCTION.—Nothing in this subsection shall be construed as—

1 “(i) requiring a Medicare+Choice plan to in-
 2 clude coverage of qualified prescription drug cov-
 3 erage; or

4 “(ii) permitting a Medicare+Choice organiza-
 5 tion from providing such coverage to an individual
 6 who has not elected such coverage under section
 7 1860A(b).

8 For purposes of this part, an individual who has not
 9 elected qualified prescription drug coverage under sec-
 10 tion 1860A(b) shall be treated as being ineligible to en-
 11 roll in a Medicare+Choice plan under this part that of-
 12 fers such coverage.

13 “(2) COMPLIANCE WITH ADDITIONAL BENEFICIARY
 14 PROTECTIONS.—With respect to the offering of qualified
 15 prescription drug coverage by a Medicare+Choice organiza-
 16 tion under a Medicare+Choice plan, the organization and
 17 plan shall meet the requirements of section 1860C, includ-
 18 ing requirements relating to information dissemination and
 19 grievance and appeals, in the same manner as they apply
 20 to a PDP sponsor and a prescription drug plan under part
 21 D and shall submit to the Administrator the information
 22 described in section 1860F(a)(2). The Administrator shall
 23 waive such requirements to the extent the Administrator
 24 determines that such requirements duplicate requirements
 25 otherwise applicable to the organization or plan under this
 26 part.

27 “(3) AVAILABILITY OF PREMIUM AND COST-SHARING
 28 SUBSIDIES FOR LOW-INCOME ENROLLEES AND DIRECT AND
 29 REINSURANCE SUBSIDY PAYMENTS FOR ORGANIZATIONS.—
 30 For provisions—

31 “(A) providing premium and cost-sharing subsidies
 32 to low-income individuals receiving qualified prescrip-
 33 tion drug coverage through a Medicare+Choice plan,
 34 see section 1860G; and

35 “(B) providing a Medicare+Choice organization
 36 with direct and insurance subsidy payments for pro-

viding qualified prescription drug coverage under this part, see section 1860H.

“(4) TRANSITION IN INITIAL ENROLLMENT PERIOD.—

Notwithstanding any other provision of this part, the annual, coordinated election period under subsection (e)(3)(B) for 2005 shall be the 6-month period beginning with November 2004.

“(5) QUALIFIED PRESCRIPTION DRUG COVERAGE;

STANDARD COVERAGE.—For purposes of this part, the terms ‘qualified prescription drug coverage’ and ‘standard coverage’ have the meanings given such terms in section 1860B.”.

(b) CONFORMING AMENDMENTS.—Section 1851 (42 U.S.C. 1395w–21) is amended—

(1) in subsection (a)(1)—

(A) by inserting “(other than qualified prescription drug benefits)” after “benefits”;

(B) by striking the period at the end of subparagraph (B) and inserting a comma; and

(C) by adding after and below subparagraph (B) the following:

“and may elect qualified prescription drug coverage in accordance with section 1860A.”; and

(2) in subsection (g)(1), by inserting “and section 1860A(c)(2)(B)” after “in this subsection”.

(c) EFFECTIVE DATE.—The amendments made by this section apply to coverage provided on or after January 1, 2005.

SEC. 103. MEDICAID AMENDMENTS.

(a) DETERMINATIONS OF ELIGIBILITY FOR LOW-INCOME SUBSIDIES.—

(1) REQUIREMENT.—Section 1902(a) (42 U.S.C. 1396a(a)) is amended—

(A) by striking “and” at the end of paragraph (64);

(B) by striking the period at the end of paragraph (65) and inserting “; and”; and

1 (C) by inserting after paragraph (65) the following
 2 new paragraph:

3 “(66) provide for making eligibility determinations
 4 under section 1935(a).”.

5 (2) NEW SECTION.—Title XIX is further amended—

6 (A) by redesignating section 1935 as section 1936;
 7 and

8 (B) by inserting after section 1934 the following
 9 new section:

10 “SPECIAL PROVISIONS RELATING TO MEDICARE PRESCRIPTION
 11 DRUG BENEFIT

12 “SEC. 1935. (a) REQUIREMENT FOR MAKING ELIGIBILITY
 13 DETERMINATIONS FOR LOW-INCOME SUBSIDIES.—As a condi-
 14 tion of its State plan under this title under section 1902(a)(66)
 15 and receipt of any Federal financial assistance under section
 16 1903(a), a State shall—

17 “(1) make determinations of eligibility for premium
 18 and cost-sharing subsidies under (and in accordance with)
 19 section 1860G;

20 “(2) inform the Administrator of the Medicare Bene-
 21 fits Administration of such determinations in cases in
 22 which such eligibility is established; and

23 “(3) otherwise provide such Administrator with such
 24 information as may be required to carry out part D of title
 25 XVIII (including section 1860G).

26 “(b) PAYMENTS FOR ADDITIONAL ADMINISTRATIVE
 27 COSTS.—

28 “(1) IN GENERAL.—The amounts expended by a State
 29 in carrying out subsection (a) are, subject to paragraph
 30 (2), expenditures reimbursable under the appropriate para-
 31 graph of section 1903(a); except that, notwithstanding any
 32 other provision of such section, the applicable Federal
 33 matching rates with respect to such expenditures under
 34 such section shall be increased as follows (but in no case
 35 shall the rate as so increased exceed 100 percent):

36 “(A) For expenditures attributable to costs in-
 37 curred during 2005, the otherwise applicable Federal

1 matching rate shall be increased by 10 percent of the
 2 percentage otherwise payable (but for this subsection)
 3 by the State.

4 “(B)(i) For expenditures attributable to costs in-
 5 curred during 2006 and each subsequent year through
 6 2013, the otherwise applicable Federal matching rate
 7 shall be increased by the applicable percent (as defined
 8 in clause (ii)) of the percentage otherwise payable (but
 9 for this subsection) by the State.

10 “(ii) For purposes of clause (i), the ‘applicable
 11 percent’ for—

12 “(I) 2006 is 20 percent; or

13 “(II) a subsequent year is the applicable per-
 14 cent under this clause for the previous year in-
 15 creased by 10 percentage points.

16 “(C) For expenditures attributable to costs in-
 17 curred after 2013, the otherwise applicable Federal
 18 matching rate shall be increased to 100 percent.

19 “(2) COORDINATION.—The State shall provide the Ad-
 20 ministrator with such information as may be necessary to
 21 properly allocate administrative expenditures described in
 22 paragraph (1) that may otherwise be made for similar eligi-
 23 bility determinations.”.

24 (b) PHASED-IN FEDERAL ASSUMPTION OF MEDICAID RE-
 25 SPONSIBILITY FOR PREMIUM AND COST-SHARING SUBSIDIES
 26 FOR DUALY ELIGIBLE INDIVIDUALS.—

27 (1) IN GENERAL.—Section 1903(a)(1) (42 U.S.C.
 28 1396b(a)(1)) is amended by inserting before the semicolon
 29 the following: “, reduced by the amount computed under
 30 section 1935(c)(1) for the State and the quarter”.

31 (2) AMOUNT DESCRIBED.—Section 1935, as inserted
 32 by subsection (a)(2), is amended by adding at the end the
 33 following new subsection:

34 “(c) FEDERAL ASSUMPTION OF MEDICAID PRESCRIPTION
 35 DRUG COSTS FOR DUALY-ELIGIBLE BENEFICIARIES.—

36 “(1) IN GENERAL.—For purposes of section
 37 1903(a)(1), for a State that is one of the 50 States or the

District of Columbia for a calendar quarter in a year (beginning with 2005) the amount computed under this subsection is equal to the product of the following:

“(A) MEDICARE SUBSIDIES.—The total amount of payments made in the quarter under section 1860G (relating to premium and cost-sharing prescription drug subsidies for low-income medicare beneficiaries) that are attributable to individuals who are residents of the State and are entitled to benefits with respect to prescribed drugs under the State plan under this title (including such a plan operating under a waiver under section 1115).

“(B) STATE MATCHING RATE.—A proportion computed by subtracting from 100 percent the Federal medical assistance percentage (as defined in section 1905(b)) applicable to the State and the quarter.

“(C) PHASE-OUT PROPORTION.—The phase-out proportion (as defined in paragraph (2)) for the quarter.

“(2) PHASE-OUT PROPORTION.—For purposes of paragraph (1)(C), the ‘phase-out proportion’ for a calendar quarter in—

“(A) 2005 is 90 percent;

“(B) a subsequent year before 2014, is the phase-out proportion for calendar quarters in the previous year decreased by 10 percentage points; or

“(C) a year after 2013 is 0 percent.”.

(c) MEDICAID PROVIDING WRAP-AROUND BENEFITS.—Section 1935, as so inserted and amended, is further amended by adding at the end the following new subsection:

“(d) ADDITIONAL PROVISIONS.—

“(1) MEDICAID AS SECONDARY PAYOR.—In the case of an individual who is entitled to qualified prescription drug coverage under a prescription drug plan under part D of title XVIII (or under a Medicare+Choice plan under part C of such title) and medical assistance for prescribed drugs under this title, medical assistance shall continue to be pro-

vided under this title for prescribed drugs to the extent payment is not made under the prescription drug plan or the Medicare+Choice plan selected by the individual.

“(2) CONDITION.—A State may require, as a condition for the receipt of medical assistance under this title with respect to prescription drug benefits for an individual eligible to obtain qualified prescription drug coverage described in paragraph (1), that the individual elect qualified prescription drug coverage under section 1860A.”.

(d) TREATMENT OF TERRITORIES.—

(1) IN GENERAL.—Section 1935, as so inserted and amended, is further amended—

(A) in subsection (a) in the matter preceding paragraph (1), by inserting “subject to subsection (e)” after “section 1903(a)”;

(B) in subsection (c)(1), by inserting “subject to subsection (e)” after “1903(a)(1)”; and

(C) by adding at the end the following new subsection:

“(e) TREATMENT OF TERRITORIES.—

“(1) IN GENERAL.—In the case of a State, other than the 50 States and the District of Columbia—

“(A) the previous provisions of this section shall not apply to residents of such State; and

“(B) if the State establishes a plan described in paragraph (2) (for providing medical assistance with respect to the provision of prescription drugs to medicare beneficiaries), the amount otherwise determined under section 1108(f) (as increased under section 1108(g)) for the State shall be increased by the amount specified in paragraph (3).

“(2) PLAN.—The plan described in this paragraph is a plan that—

“(A) provides medical assistance with respect to the provision of covered outpatient drugs (as defined in section 1860B(f)) to low-income medicare beneficiaries; and

“(B) assures that additional amounts received by the State that are attributable to the operation of this subsection are used only for such assistance.

“(3) INCREASED AMOUNT.—

“(A) IN GENERAL.—The amount specified in this paragraph for a State for a year is equal to the product of—

“(i) the aggregate amount specified in subparagraph (B); and

“(ii) the amount specified in section 1108(g)(1) for that State, divided by the sum of the amounts specified in such section for all such States.

“(B) AGGREGATE AMOUNT.—The aggregate amount specified in this subparagraph for—

“(i) 2005, is equal to \$20,000,000; or

“(ii) a subsequent year, is equal to the aggregate amount specified in this subparagraph for the previous year increased by annual percentage increase specified in section 1860B(b)(5) for the year involved.

“(4) REPORT.—The Administrator shall submit to Congress a report on the application of this subsection and may include in the report such recommendations as the Administrator deems appropriate.”.

(2) CONFORMING AMENDMENT.—Section 1108(f) (42 U.S.C. 1308(f)) is amended by inserting “and section 1935(e)(1)(B)” after “Subject to subsection (g)”.

SEC. 104. MEDIGAP TRANSITION.

(a) IN GENERAL.—Section 1882 (42 U.S.C. 1395ss) is amended by adding at the end the following new subsection:

“(v) COVERAGE OF PRESCRIPTION DRUGS.—

“(1) IN GENERAL.—Notwithstanding any other provision of law, except as provided in paragraph (3) no new medicare supplemental policy that provides coverage of expenses for prescription drugs may be issued under this section on or after January 1, 2005, to an individual unless

1 it replaces a medicare supplemental policy that was issued
 2 to that individual and that provided some coverage of ex-
 3 penses for prescription drugs.

4 “(2) ISSUANCE OF SUBSTITUTE POLICIES IF OBTAIN
 5 PRESCRIPTION DRUG COVERAGE UNDER PART D.—

6 “(A) IN GENERAL.—The issuer of a medicare sup-
 7 plemental policy—

8 “(i) may not deny or condition the issuance or
 9 effectiveness of a medicare supplemental policy that
 10 has a benefit package classified as ‘A’, ‘B’, ‘C’, ‘D’,
 11 ‘E’, ‘F’, or ‘G’ (under the standards established
 12 under subsection (p)(2)) and that is offered and is
 13 available for issuance to new enrollees by such
 14 issuer;

15 “(ii) may not discriminate in the pricing of
 16 such policy, because of health status, claims experi-
 17 ence, receipt of health care, or medical condition;
 18 and

19 “(iii) may not impose an exclusion of benefits
 20 based on a pre-existing condition under such policy,
 21 in the case of an individual described in subparagraph
 22 (B) who seeks to enroll under the policy not later than
 23 63 days after the date of the termination of enrollment
 24 described in such paragraph and who submits evidence
 25 of the date of termination or disenrollment along with
 26 the application for such medicare supplemental policy.

27 “(B) INDIVIDUAL COVERED.—An individual de-
 28 scribed in this subparagraph is an individual who—

29 “(i) enrolls in a prescription drug plan under
 30 part D; and

31 “(ii) at the time of such enrollment was en-
 32 rolled and terminates enrollment in a medicare sup-
 33 plemental policy which has a benefit package classi-
 34 fied as ‘H’, ‘I’, or ‘J’ under the standards referred
 35 to in subparagraph (A)(i) or terminates enrollment
 36 in a policy to which such standards do not apply
 37 but which provides benefits for prescription drugs.

“(C) ENFORCEMENT.—The provisions of paragraph (4) of subsection (s) shall apply with respect to the requirements of this paragraph in the same manner as they apply to the requirements of such subsection.

“(3) NEW STANDARDS.—In applying subsection (p)(1)(E) (including permitting the NAIC to revise its model regulations in response to changes in law) with respect to the change in benefits resulting from title I of the Medicare Modernization and Prescription Drug Act of 2002, with respect to policies issued to individuals who are enrolled under part D, the changes in standards shall provide for at least two benefit packages (other than the core benefit package) that may provide for coverage of cost-sharing with respect to qualified prescription drug coverage under such part, except that such coverage may not cover the prescription drug deductible under such part. Two benefit packages shall be consistent with the following:

“(A) FIRST NEW POLICY.—The policy described in this subparagraph has the following benefits, notwithstanding any other provision of this section relating to a core benefit package:

“(i) Coverage of 50 percent of the cost-sharing otherwise applicable, except coverage of 100 percent of any cost-sharing otherwise applicable for preventive benefits.

“(ii) No coverage of the part B deductible.

“(iii) Coverage for all hospital coinsurance for long stays (as in the current core benefit package).

“(iv) A limitation on annual out-of-pocket expenditures to \$4,000 in 2005 (or, in a subsequent year, to such limitation for the previous year increased by an appropriate inflation adjustment specified by the Secretary).

“(B) SECOND NEW POLICY.—The policy described in this subparagraph has the same benefits as the policy described in subparagraph (A), except as follows:

“ (i) Substitute ‘75 percent’ for ‘50 percent’ in clause (i) of such subparagraph.

“ (ii) Substitute ‘\$2,000’ for ‘\$4,000’ in clause (iv) of such subparagraph.

“(4) CONSTRUCTION.—Any provision in this section or in a medicare supplemental policy relating to guaranteed renewability of coverage shall be deemed to have been met through the offering of other coverage under this subsection.”.

SEC. 105. MEDICARE PRESCRIPTION DRUG DISCOUNT CARD ENDORSEMENT PROGRAM.

Title XVIII is amended by inserting after section 1806 the following new section:

“MEDICARE PRESCRIPTION DRUG DISCOUNT CARD
ENDORSEMENT PROGRAM

“SEC. 1807. (a) IN GENERAL.—The Secretary (or the Medicare Benefits Administrator pursuant to section 1808(c)(3)(C)) shall establish a program—

“(1) to endorse prescription drug discount card programs that meet the requirements of this section; and

“(2) to make available to medicare beneficiaries information regarding such endorsed programs.

“(b) REQUIREMENTS FOR ENDORSEMENT.—The Secretary may not endorse a prescription drug discount card program under this section unless the program meets the following requirements:

“(1) SAVINGS TO MEDICARE BENEFICIARIES.—The program passes on to medicare beneficiaries who enroll in the program discounts on prescription drugs, including discounts negotiated with manufacturers.

“(2) PROHIBITION ON APPLICATION ONLY TO MAIL ORDER.—The program applies to drugs that are available other than solely through mail order.

“(3) BENEFICIARY SERVICES.—The program provides pharmaceutical support services, such as education and counseling, and services to prevent adverse drug interactions.

“(4) INFORMATION.—The program makes available to medicare beneficiaries through the Internet and otherwise information, including information on enrollment fees, prices charged to beneficiaries, and services offered under the program, that the Secretary identifies as being necessary to provide for informed choice by beneficiaries among endorsed programs.

“(5) DEMONSTRATED EXPERIENCE.—The entity operating the program has demonstrated experience and expertise in operating such a program or a similar program.

“(6) QUALITY ASSURANCE.—The entity has in place adequate procedures for assuring quality service under the program.

“(7) ADDITIONAL BENEFICIARY PROTECTIONS.—The program meets such additional requirements as the Secretary identifies to protect and promote the interest of medicare beneficiaries, including requirements that ensure that beneficiaries are not charged more than the lower of the negotiated retail price or the usual and customary price.

“(c) PROGRAM OPERATION.—The Secretary shall operate the program under this section consistent with the following:

“(1) PROMOTION OF INFORMED CHOICE.—In order to promote informed choice among endorsed prescription drug discount card programs, the Secretary shall provide for the dissemination of information which compares the costs and benefits of such programs in a manner coordinated with the dissemination of educational information on Medicare+Choice plans under part C.

“(2) OVERSIGHT.—The Secretary shall provide appropriate oversight to ensure compliance of endorsed programs with the requirements of this section, including verification of the discounts and services provided.

“(3) USE OF MEDICARE TOLL-FREE NUMBER.—The Secretary shall provide through the 1-800-medicare toll free telephone number for the receipt and response to inquiries

and complaints concerning the program and programs endorsed under this section.

“(4) DISQUALIFICATION FOR ABUSIVE PRACTICES.—

The Secretary shall revoke the endorsement of a program that the Secretary determines no longer meets the requirements of this section or that has engaged in false or misleading marketing practices.

“(5) ENROLLMENT PRACTICES.—A medicare bene-

ficiary may not be enrolled in more than one endorsed program at any time.

“(d) TRANSITION.—The Secretary shall provide for an ap-

propriate transition and discontinuation of the program under this section at the time prescription drug benefits first become available under part D.

“(e) AUTHORIZATION OF APPROPRIATIONS.—There are

authorized to be appropriated such sums as may be necessary to carry out the program under this section.”.

TITLE II—MEDICARE+CHOICE REVITALIZATION AND MEDICARE+CHOICE COMPETITION PROGRAM

Subtitle A—Medicare+Choice Revitalization

SEC. 201. MEDICARE+CHOICE IMPROVEMENTS.

(a) EQUALIZING PAYMENTS BETWEEN FEE-FOR-SERVICE AND MEDICARE+CHOICE.—

(1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C. 1395w-23(c)(1)) is amended by adding at the end the following:

“(D) BASED ON 100 PERCENT OF FEE-FOR-SERVICE COSTS.—

“(i) IN GENERAL.—For 2003 and 2004, the adjusted average per capita cost for the year involved, determined under section 1876(a)(4) for the Medicare+Choice payment area for services covered under parts A and B for individuals entitled

to benefits under part A and enrolled under part B who are not enrolled in a Medicare+Choice plan under this part for the year, but adjusted to exclude costs attributable to payments under section 1886(h).

“(ii) INCLUSION OF COSTS OF VA AND DOD MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the adjusted average per capita cost under clause (i) for a year, such cost shall be adjusted to include the Secretary’s estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Veterans Affairs or the Department of Defense.”.

(2) CONFORMING AMENDMENT.—Such section is further amended, in the matter before subparagraph (A), by striking “or (C)” and inserting “(C), or (D)”.

(b) REVISION OF BLEND.—

(1) REVISION OF NATIONAL AVERAGE USED IN CALCULATION OF BLEND.—Section 1853(c)(4)(B)(i)(II) (42 U.S.C. 1395w–23(c)(4)(B)(i)(II)) is amended by inserting “who (with respect to determinations for 2003 and for 2004) are enrolled in a Medicare+Choice plan” after “the average number of medicare beneficiaries”.

(2) CHANGE IN BUDGET NEUTRALITY.—Section 1853(c) (42 U.S.C. 1395w–23(c)) is amended—

(A) in paragraph (1)(A), by inserting “(for a year before 2003)” after “multiplied”; and

(B) in paragraph (5), by inserting “(before 2003)” after “for each year”.

(c) REVISION IN MINIMUM PERCENTAGE INCREASE FOR 2003 AND 2004.—Section 1853(c)(1)(C) (42 U.S.C. 1395w–23(c)(1)(C)) is amended by striking clause (iv) and inserting the following:

“(iv) For 2002, 102 percent of the annual Medicare+Choice capitation rate under this paragraph for the area for 2001.

“(v) For 2003 and 2004, 103 percent of the annual Medicare+Choice capitation rate under this paragraph for the area for the previous year.

“(iv) For 2005 and each succeeding year, 102 percent of the annual Medicare+Choice capitation rate under this paragraph for the area for the previous year.”.

(d) INCLUSION OF COSTS OF DOD AND VA MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES IN CALCULATION OF MEDICARE+CHOICE PAYMENT RATES.—Section 1853(c)(3) (42 U.S.C. 1395w–23(c)(3)) is amended—

(1) in subparagraph (A), by striking “subparagraph (B)” and inserting “subparagraphs (B) and (E)”, and

(2) by adding at the end the following new subparagraph:

“(E) INCLUSION OF COSTS OF DOD AND VA MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the area-specific Medicare+Choice capitation rate under subparagraph (A) for a year (beginning with 2003), the annual per capita rate of payment for 1997 determined under section 1876(a)(1)(C) shall be adjusted to include in the rate the Secretary’s estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense or the Department of Veterans Affairs.”.

(e) ANNOUNCEMENT OF REVISED MEDICARE+CHOICE PAYMENT RATES.—Within 2 weeks after the date of the enactment of this Act, the Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties) Medicare+Choice capitation rates under section 1853

of the Social Security Act (42 U.S.C. 1395w-23) for 2003, revised in accordance with the provisions of this section.

(f) MEDPAC STUDY OF AAPCC.—

(1) STUDY.—The Medicare Payment Advisory Commission shall conduct a study that assesses the method used for determining the adjusted average per capita cost (AAPCC) under section 1876(a)(4) of the Social Security Act (42 U.S.C. 1395mm(a)(4)). Such study shall examine—

(A) the bases for variation in such costs between different areas, including differences in input prices, utilization, and practice patterns;

(B) the appropriate geographic area for payment under the Medicare+Choice program under part C of title XVIII of such Act; and

(C) the accuracy of risk adjustment methods in reflecting differences in costs of providing care to different groups of beneficiaries served under such program.

(2) REPORT.—Not later than 9 months after the date of the enactment of this Act, the Commission shall submit to Congress a report on the study conducted under paragraph (1). Such report shall include recommendations regarding changes in the methods for computing the adjusted average per capita cost among different areas.

SEC. 202. MAKING PERMANENT CHANGE IN MEDICARE+CHOICE REPORTING DEADLINES AND ANNUAL, COORDINATED ELECTION PERIOD.

(a) CHANGE IN REPORTING DEADLINE.—Section 1854(a)(1) (42 U.S.C. 1395w-24(a)(1)), as amended by section 532(b)(1) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, is amended by striking “2002, 2003, and 2004 (or July 1 of each other year)” and inserting “2002 and each subsequent year (or July 1 of each year before 2002)”.

(b) DELAY IN ANNUAL, COORDINATED ELECTION PERIOD.—Section 1851(e)(3)(B) (42 U.S.C. 1395w–21(e)(3)(B)), as amended by section 532(c)(1)(A) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, is amended by striking “and after 2005, the month of November before such year and with respect to 2003, 2004, and 2005” and inserting “, the month of November before such year and with respect to 2003 and any subsequent year”.

(c) ANNUAL ANNOUNCEMENT OF PAYMENT RATES.—Section 1853(b)(1) (42 U.S.C. 1395w–23(b)(1)), as amended by section 532(d)(1) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, is amended by striking “and after 2005 not later than March 1 before the calendar year concerned and for 2004 and 2005” and inserting “not later than March 1 before the calendar year concerned and for 2004 and each subsequent year”.

(d) REQUIRING PROVISION OF AVAILABLE INFORMATION COMPARING PLAN OPTIONS.—The first sentence of section 1851(d)(2)(A)(ii) (42 U.S.C. 1395w–21(d)(2)(A)(ii)) is amended by inserting before the period the following: “to the extent such information is available at the time of preparation of materials for the mailing”.

SEC. 203. AVOIDING DUPLICATIVE STATE REGULATION.

(a) IN GENERAL.—Section 1856(b)(3) (42 U.S.C. 1395w–26(b)(3)) is amended to read as follows:

“(3) RELATION TO STATE LAWS.—The standards established under this subsection shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to Medicare+Choice plans which are offered by Medicare+Choice organizations under this part.”.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act.

SEC. 204. SPECIALIZED MEDICARE+CHOICE PLANS FOR SPECIAL NEEDS BENEFICIARIES.

(a) TREATMENT AS COORDINATED CARE PLAN.—Section 1851(a)(2)(A) (42 U.S.C. 1395w–21(a)(2)(A)) is amended by adding at the end the following new sentence: “Specialized Medicare+Choice plans for special needs beneficiaries (as defined in section 1859(b)(4)) may be any type of coordinated care plan.”.

(b) SPECIALIZED MEDICARE+CHOICE PLAN FOR SPECIAL NEEDS BENEFICIARIES DEFINED.—Section 1859(b) (42 U.S.C. 1395w–29(b)) is amended by adding at the end the following new paragraph:

“(4) SPECIALIZED MEDICARE+CHOICE PLANS FOR SPECIAL NEEDS BENEFICIARIES.—

“(A) IN GENERAL.—The term ‘specialized Medicare+Choice plan for special needs beneficiaries’ means a Medicare+Choice plan that exclusively serves special needs beneficiaries (as defined in subparagraph (B)).

“(B) SPECIAL NEEDS BENEFICIARY.—The term ‘special needs beneficiary’ means a Medicare+Choice eligible individual who—

“(i) is institutionalized (as defined by the Secretary);

“(ii) is entitled to medical assistance under a State plan under title XIX; or

“(iii) meets such requirements as the Secretary may determine would benefit from enrollment in such a specialized Medicare+Choice plan described in subparagraph (A) for individuals with severe or disabling chronic conditions.”.

(c) RESTRICTION ON ENROLLMENT PERMITTED.—Section 1859 (42 U.S.C. 1395w–29) is amended by adding at the end the following new subsection:

“(f) RESTRICTION ON ENROLLMENT FOR SPECIALIZED MEDICARE+CHOICE PLANS FOR SPECIAL NEEDS BENEFICIARIES.—In the case of a specialized Medicare+Choice plan

(as defined in subsection (b)(4)), notwithstanding any other provision of this part and in accordance with regulations of the Secretary and for periods before January 1, 2007, the plan may restrict the enrollment of individuals under the plan to individuals who are within one or more classes of special needs beneficiaries.”.

(d) REPORT TO CONGRESS.—Not later than December 31, 2005, the Medicare Benefits Administrator shall submit to Congress a report that assesses the impact of specialized Medicare+Choice plans for special needs beneficiaries on the cost and quality of services provided to enrollees. Such report shall include an assessment of the costs and savings to the medicare program as a result of amendments made by subsections (a), (b), and (c).

(e) EFFECTIVE DATES.—

(1) IN GENERAL.—The amendments made by subsections (a), (b), and (c) shall take effect upon the date of the enactment of this Act.

(2) DEADLINE FOR ISSUANCE OF REQUIREMENTS FOR SPECIAL NEEDS BENEFICIARIES; TRANSITION.—No later than 6 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue final regulations to establish requirements for special needs beneficiaries under section 1859(b)(4)(B)(iii) of the Social Security Act, as added by subsection (b).

SEC. 205. MEDICARE MSAS.

(a) EXEMPTION FROM QUALITY ASSURANCE PROGRAM REQUIREMENT.—

(1) IN GENERAL.—Section 1852(e)(1) (42 U.S.C. 1395w–22(e)(1)) is amended by inserting “(other than MSA plans)” after “Medicare+Choice plans”.

(2) CONFORMING AMENDMENTS.—Section 1852 (42 U.S.C. 1395w–22) is amended—

(A) in subsection (c)(1)(I), by inserting before the period at the end the following: “if required under such section”; and

1 (B) in subparagraphs (A) and (B) of subsection
 2 (e)(2), by striking “, a non-network MSA plan,” and
 3 “, NON-NETWORK MSA PLANS,” each place it appears.

4 (b) MAKING PROGRAM PERMANENT AND ELIMINATING
 5 CAP.—Section 1851(b)(4) (42 U.S.C. 1395w–21(b)(4)) is
 6 amended—

7 (1) in the heading of subparagraph (A), by striking
 8 “ON A DEMONSTRATION BASIS”;

9 (2) by striking the first sentence of subparagraph (A);
 10 and

11 (3) by striking the second sentence of subparagraph
 12 (C).

13 (c) APPLYING LIMITATIONS ON BALANCE BILLING.—Sec-
 14 tion 1852(k)(1) (42 U.S.C. 1395w–22(k)(1)) is amended by in-
 15 serting “or with an organization offering a MSA plan” after
 16 “section 1851(a)(2)(A)”.

17 (d) ADDITIONAL AMENDMENT.—Section 1851(e)(5)(A)
 18 (42 U.S.C. 1395w–21(e)(5)(A)) is amended—

19 (1) by adding “or” at the end of clause (i);

20 (2) by striking “, or” at the end of clause (ii) and in-
 21 serting a semicolon; and

22 (3) by striking clause (iii).

23 **SEC. 206. EXTENSION OF REASONABLE COST AND SHMO**
 24 **CONTRACTS.**

25 (a) REASONABLE COST CONTRACTS.—

26 (1) IN GENERAL.—Section 1876(h)(5)(C) (42 U.S.C.
 27 1395mm(h)(5)(C)) is amended—

28 (A) by inserting “(i)” after “(C)”;

29 (B) by inserting before the period the following: “,
 30 except (subject to clause (ii)) in the case of a contract
 31 for an area which is not covered in the service area of
 32 1 or more coordinated care Medicare+Choice plans
 33 under part C”; and

34 (C) by adding at the end the following new clause:
 35 “(ii) In the case in which—

“(I) a reasonable cost reimbursement contract includes an area in its service area as of a date that is after December 31, 2003;

“(II) such area is no longer included in such service area after such date by reason of the operation of clause (i) because of the inclusion of such area within the service area of a Medicare+Choice plan; and

“(III) all Medicare+Choice plans subsequently terminate coverage in such area;

such reasonable cost reimbursement contract may be extended and renewed to cover such area (so long as it is not included in the service area of any Medicare+Choice plan).”.

(2) STUDY.—The Medicare Benefits Administrator shall conduct a study of an appropriate transition for plans offered under reasonable cost contracts under section 1876 of the Social Security Act on and after January 1, 2005. Such a transition may take into account whether there are one or more coordinated care Medicare+Choice plans being offered in the areas involved. Not later than February 1, 2004, the Administrator shall submit to Congress a report on such study and shall include recommendations regarding any changes in the amendment made by paragraph (1) as the Administrator determines to be appropriate.

(b) EXTENSION OF SOCIAL HEALTH MAINTENANCE ORGANIZATION (SHMO) DEMONSTRATION PROJECT.—

(1) IN GENERAL.—Section 4018(b)(1) of the Omnibus Budget Reconciliation Act of 1987 is amended by striking “the date that is 30 months after the date that the Secretary submits to Congress the report described in section 4014(c) of the Balanced Budget Act of 1997” and inserting “December 31, 2004”.

(2) SHMOS OFFERING MEDICARE+CHOICE PLANS.—Nothing in such section 4018 shall be construed as preventing a social health maintenance organization from offering a Medicare+Choice plan under part C of title XVIII of the Social Security Act.

Subtitle B—Medicare+Choice Competition Program

SEC. 211. MEDICARE+CHOICE COMPETITION PROGRAM.

(a) SUBMISSION OF BID AMOUNTS.—Section 1854 (42 U.S.C. 1395w–24) is amended—

(1) by amending the heading to read as follows:

“SUBMISSION OF BID AMOUNTS”;

(2) in subsection (a)(1)(A)—

(A) by striking “(A)” and inserting “(A)(i) if the following year is before 2005,”; and

(B) by inserting before the semicolon at the end the following: “ or (ii) if the following year is 2005 or later, the information described in paragraph (6)(A)”;

and

(3) by adding at the end of subsection (a) the following:

“(6) SUBMISSION OF BID AMOUNTS BY MEDICARE+CHOICE ORGANIZATIONS.—

“(A) INFORMATION TO BE SUBMITTED.—The information described in this subparagraph is as follows:

“(i) The monthly aggregate bid amount for provision of all items and services under this part and the actuarial basis for determining such amount.

“(ii) The proportions of such bid amount that are attributable to—

“(I) the provision of statutory non-drug benefits (such portion referred to in this part as the ‘unadjusted non-drug monthly bid amount’);

“(II) the provision of statutory prescription drug benefits; and

“(III) the provision of non-statutory benefits;

and the actuarial basis for determining such proportions.

“(iii) Such additional information as the Administrator may require to verify the actuarial bases described in clauses (i) and (ii).

“(B) STATUTORY BENEFITS DEFINED.—For purposes of this part:

“(i) The term ‘statutory non-drug benefits’ means benefits under parts A and B.

“(ii) The term ‘statutory prescription drug benefits’ means benefits under part D.

“(iii) The term ‘statutory benefits’ means statutory prescription drug benefits and statutory non-drug benefits.

“(C) ACCEPTANCE AND NEGOTIATION OF BID AMOUNTS.—The Administrator has the authority to negotiate regarding monthly bid amounts submitted under subparagraph (A) (and the proportion described in subparagraph (A)(ii)). The Administrator may reject such a bid amount or proportion if the Administrator determines that such amount or proportion is not supported by the actuarial bases provided under subparagraph (A).”.

(b) PROVIDING FOR BENEFICIARY SAVINGS FOR CERTAIN PLANS.—

(1) IN GENERAL.—Section 1854(b) (42 U.S.C. 1395w-24(b)) is amended—

(A) by adding at the end of paragraph (1) the following new subparagraph:

“(C) BENEFICIARY REBATE RULE.—

“(i) REQUIREMENT.—The Medicare+Choice plan shall provide to the enrollee a monthly rebate equal to 75 percent of the average per capita savings (if any) described in paragraph (3) applicable to the plan and year involved.

“(iii) FORM OF REBATE.—A rebate required under this subparagraph shall be provided—

“(I) through the crediting of the amount of the rebate towards the Medicare+Choice

1 monthly supplementary beneficiary premium or
 2 the premium imposed for prescription drug cov-
 3 erage under part D;

4 “(II) through a direct monthly payment
 5 (through electronic funds transfer or other-
 6 wise); or

7 “(III) through other means approved by
 8 the Medicare Benefits Administrator,
 9 or any combination thereof.”; and

10 (B) by adding at the end the following new para-
 11 graph:

12 “(3) COMPUTATION OF AVERAGE PER CAPITA MONTH-
 13 LY SAVINGS.—For purposes of paragraph (1)(C)(i), the av-
 14 erage per capita monthly savings referred to in such para-
 15 graph for a Medicare+Choice plan and year is computed
 16 as follows:

17 “(A) DETERMINATION OF STATE-WIDE AVERAGE
 18 RISK ADJUSTMENT.—

19 “(i) IN GENERAL.—The Medicare Benefits Ad-
 20 ministrator shall determine, at the same time rates
 21 are promulgated under section 1853(b)(1) (begin-
 22 ning with 2005), for each State the average of the
 23 risk adjustment factors to be applied to enrollees
 24 under section 1853(a)(1)(A) in that State. In the
 25 case of a State in which a Medicare+Choice plan
 26 was offered in the previous year, the Administrator
 27 may compute such average based upon risk adjust-
 28 ment factors applied in that State in a previous
 29 year.

30 “(ii) TREATMENT OF NEW STATES.—In the
 31 case of a State in which no Medicare+Choice plan
 32 was offered in the previous year, the Administrator
 33 shall estimate such average. In making such esti-
 34 mate, the Administrator may use average risk ad-
 35 justment factors applied to comparable States or
 36 applied on a national basis.

“(B) DETERMINATION OF RISK ADJUSTED BENCHMARK AND RISK-ADJUSTED BID.—For each Medicare+Choice plan offered in a State, the Administrator shall—

“(i) adjust the fee-for-service area-specific non-drug benchmark amount by the applicable average risk adjustment factor computed under subparagraph (A); and

“(ii) adjust the unadjusted non-drug monthly bid amount by such applicable average risk adjustment factor.

“(C) DETERMINATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—The average per capita monthly savings described in this subparagraph is equal to the amount (if any) by which—

“(i) the risk-adjusted benchmark amount computed under subparagraph (B)(i), exceeds

“(ii) the risk-adjusted bid computed under subparagraph (B)(ii).

“(D) AUTHORITY TO DETERMINE RISK ADJUSTMENT FOR AREAS OTHER THAN STATES.—The Administrator may provide for the determination and application of risk adjustment factors under this paragraph on the basis of areas other than States.”.

(2) COMPUTATION OF FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG BENCHMARK.—Section 1853 (42 U.S.C. 1395w-23) is amended by adding at the end the following new subsection:

“(j) COMPUTATION OF FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG BENCHMARK AMOUNT.—For purposes of this part, the term ‘fee-for-service area-specific non-drug benchmark amount’ means, with respect to a Medicare+Choice payment area for a month in a year, an amount equal to the greater of the following (but in no case less than $\frac{1}{12}$ of the rate computed under subsection (c)(1), without regard to subparagraph (A), for the year):

“(1) BASED ON 100 PERCENT OF FEE-FOR-SERVICE COSTS IN THE AREA.—An amount equal to $\frac{1}{12}$ of 100 percent (for 2005 through 2007, or 95 percent for 2008 and years thereafter) of the adjusted average per capita cost for the year involved, determined under section 1876(a)(4) for the Medicare+Choice payment area, for the area and the year involved, for services covered under parts A and B for individuals entitled to benefits under part A and enrolled under part B who are not enrolled in a Medicare+Choice plan under this part for the year, and adjusted to exclude from such cost the amount the Medicare Benefits Administrator estimates is payable for costs described in subclauses (I) and (II) of subsection (c)(3)(C)(i) for the year involved and also adjusted in the manner described in subsection (c)(1)(D)(ii) (relating to inclusion of costs of VA and DOD military facility services to medicare-eligible beneficiaries).

“(2) MINIMUM MONTHLY AMOUNT.—The minimum amount specified in this paragraph is the amount specified in subsection (c)(1)(B)(iv) for the year involved.”.

(c) PAYMENT OF PLANS BASED ON BID AMOUNTS.—

(1) IN GENERAL.—Section 1853(a)(1)(A) (42 U.S.C. 1395w-23) is amended by striking “in an amount” and all that follows and inserting the following: “in an amount determined as follows:

“(i) PAYMENT BEFORE 2005.—For years before 2005, the payment amount shall be equal to $\frac{1}{12}$ of the annual Medicare+Choice capitation rate (as calculated under subsection (c)) with respect to that individual for that area, reduced by the amount of any reduction elected under section 1854(f)(1)(E) and adjusted under clause (iii).

“(ii) PAYMENT FOR STATUTORY NON-DRUG BENEFITS BEGINNING WITH 2005.—For years beginning with 2005—

“(I) PLANS WITH BIDS BELOW BENCHMARK.—In the case of a plan for which there are average per capita monthly savings de-

scribed in section 1854(b)(3)(C), the payment under this subsection is equal to the unadjusted non-drug monthly bid amount, adjusted under clause (iii), plus the amount of the monthly rebate computed under section 1854(b)(1)(C)(i) for that plan and year.

“(II) PLANS WITH BIDS AT OR ABOVE BENCHMARK.—In the case of a plan for which there are no average per capita monthly savings described in section 1854(b)(3)(C), the payment amount under this subsection is equal to the fee-for-service area-specific non-drug benchmark amount, adjusted under clause (iii).

“(iii) DEMOGRAPHIC ADJUSTMENT, INCLUDING ADJUSTMENT FOR HEALTH STATUS.—The Administrator shall adjust the payment amount under clause (i), the unadjusted non-drug monthly bid amount under clause (ii)(I), and the fee-for-service area-specific non-drug benchmark amount under clause (ii)(II) for such risk factors as age, disability status, gender, institutional status, and such other factors as the Administrator determines to be appropriate, including adjustment for health status under paragraph (3), so as to ensure actuarial equivalence. The Administrator may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence.

“(iv) REFERENCE TO SUBSIDY PAYMENT FOR STATUTORY DRUG BENEFITS.—In the case in which an enrollee is enrolled under part D, the Medicare+Choice organization also is entitled to a subsidy payment amount under section 1860H.”.

(d) CONFORMING AMENDMENTS.—

(1) PROTECTION AGAINST BENEFICIARY SELECTION.—Section 1852(b)(1)(A) (42 U.S.C. 1395w–22(b)(1)(A)) is amended by adding at the end the following: “The Admin-

1 istrator shall not approve a plan of an organization if the
 2 Administrator determines that the benefits are designed to
 3 substantially discourage enrollment by certain
 4 Medicare+Choice eligible individuals with the organiza-
 5 tion.”.

6 (2) CONFORMING AMENDMENT TO PREMIUM TERMI-
 7 NOLOGY.—Subparagraphs (A) and (B) of section
 8 1854(b)(2) (42 U.S.C. 1395w–24(b)(2)) are amended to
 9 read as follows:

10 “(A) MEDICARE+CHOICE MONTHLY BASIC BENE-
 11 FICIARY PREMIUM.—The term ‘Medicare+Choice
 12 monthly basic beneficiary premium’ means, with re-
 13 spect to a Medicare+Choice plan—

14 “(i) described in section 1853(a)(1)(A)(ii)(I)
 15 (relating to plans providing rebates), zero; or

16 “(ii) described in section 1853(a)(1)(A)(ii)(II),
 17 the amount (if any) by which the unadjusted non-
 18 drug monthly bid amount exceeds the fee-for-serv-
 19 ice area-specific non-drug benchmark amount.

20 “(B) MEDICARE+CHOICE MONTHLY SUPPLE-
 21 MENTAL BENEFICIARY PREMIUM.—The term
 22 ‘Medicare+Choice monthly supplemental beneficiary
 23 premium’ means, with respect to a Medicare+Choice
 24 plan, the portion of the aggregate monthly bid amount
 25 submitted under clause (i) of subsection (a)(6)(A) for
 26 the year that is attributable under such section to the
 27 provision of nonstatutory benefits.”.

28 (3) REQUIREMENT FOR UNIFORM BID AMOUNTS.—
 29 Section 1854(c) (42 U.S.C. 1395w–24(c)) is amended to
 30 read as follows:

31 “(c) UNIFORM BID AMOUNTS.—The Medicare+Choice
 32 monthly bid amount submitted under subsection (a)(6) of a
 33 Medicare+Choice organization under this part may not vary
 34 among individuals enrolled in the plan.”.

35 (4) PERMITTING BENEFICIARY REBATES.—

36 (A) Section 1851(h)(4)(A) (42 U.S.C. 1395w–
 37 21(h)(4)(A)) is amended by inserting “except as pro-

vided under section 1854(b)(1)(C)” after “or otherwise”.

(B) Section 1854(d) (42 U.S.C. 1395w–24(d)) is amended by inserting “, except as provided under subsection (b)(1)(C),” after “and may not provide”.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to payments and premiums for months beginning with January 2005.

SEC. 212. DEMONSTRATION PROGRAM FOR COMPETITIVE-DEMONSTRATION AREAS.

(a) IDENTIFICATION OF COMPETITIVE-DEMONSTRATION AREAS FOR DEMONSTRATION PROGRAM; COMPUTATION OF CHOICE NON-DRUG BENCHMARKS.—Section 1853, as amended by section 211(b)(2), is amended by adding at the end the following new subsection:

“(k) ESTABLISHMENT OF COMPETITIVE DEMONSTRATION PROGRAM.—

“(1) DESIGNATION OF COMPETITIVE-DEMONSTRATION AREAS AS PART OF PROGRAM.—

“(A) IN GENERAL.—For purposes of this part, the Administrator shall establish a demonstration program under which the Administrator designates Medicare+Choice areas as competitive-demonstration areas consistent with the following limitations:

“(i) LIMITATION ON NUMBER OF AREAS THAT MAY BE DESIGNATED.—The Administrator may not designate more than 4 areas as competitive-demonstration areas.

“(ii) LIMITATION ON PERIOD OF DESIGNATION OF ANY AREA.—The Administrator may not designate any area as a competitive-demonstration area for a period of more than 2 years.

The Administrator has the discretion to decide whether or not to designate as a competitive-demonstration area an area that qualifies for such designation.

“(B) QUALIFICATIONS FOR DESIGNATION.—For purposes of this title, a Medicare+Choice area (which

1 is a metropolitan statistical area or other area with a
 2 substantial number of Medicare+Choice enrollees) may
 3 not be designated as a ‘competitive-demonstration area’
 4 for a 2-year period beginning with a year unless the
 5 Administrator determines, by such date before the be-
 6 ginning of the year as the Administrator determines
 7 appropriate, that—

8 “(i) there will be offered during the open en-
 9 rollment period under this part before the begin-
 10 ning of the year at least 2 Medicare+Choice plans
 11 (in addition to the fee-for-service program under
 12 parts A and B), each offered by a different
 13 Medicare+Choice organization; and

14 “(ii) during March of the previous year at
 15 least 50 percent of the number of Medicare+Choice
 16 eligible individuals who reside in the area were en-
 17 rolled in a Medicare+Choice plan.

18 “(2) CHOICE NON-DRUG BENCHMARK AMOUNT.—For
 19 purposes of this part, the term ‘choice non-drug benchmark
 20 amount’ means, with respect to a Medicare+Choice pay-
 21 ment area for a month in a year, the sum of the 2 compo-
 22 nents described in paragraph (3) for the area and year.
 23 The Administrator shall compute such benchmark amount
 24 for each competitive-demonstration area before the begin-
 25 ning of each annual, coordinated election period under sec-
 26 tion 1851(e)(3)(B) for each year (beginning with 2005) in
 27 which it is designated as such an area.

28 “(3) 2 COMPONENTS.—For purposes of paragraph (2),
 29 the 2 components described in this paragraph for an area
 30 and a year are the following:

31 “(A) FEE-FOR-SERVICE COMPONENT WEIGHTED
 32 BY NATIONAL FEE-FOR-SERVICE MARKET SHARE.—The
 33 product of the following:

34 “(i) NATIONAL FEE-FOR-SERVICE MARKET
 35 SHARE.—The national fee-for-service market share
 36 percentage (determined under paragraph (5)) for
 37 the year.

“(ii) FEE-FOR-SERVICE AREA-SPECIFIC NON-
 DRUG BID.—The fee-for-service area-specific non-
 drug bid (as defined in paragraph (6)) for the area
 and year.

“(B) M+C COMPONENT WEIGHTED BY NATIONAL
 MEDICARE+CHOICE MARKET SHARE.—The product of
 the following:

“(i) NATIONAL MEDICARE+CHOICE MARKET
 SHARE.—1 minus the national fee-for-service mar-
 ket share percentage for the year.

“(ii) WEIGHTED AVERAGE OF PLAN BIDS IN
 AREA.—The weighted average of the plan bids for
 the area and year (as determined under paragraph
 (4)(A)).

“(4) DETERMINATION OF WEIGHTED AVERAGE BIDS
 FOR AN AREA.—

“(A) IN GENERAL.—For purposes of paragraph
 (3)(B)(ii), the weighted average of plan bids for an
 area and a year is the sum of the following products
 for Medicare+Choice plans described in subparagraph
 (C) in the area and year:

“(i) PROPORTION OF EACH PLAN’S ENROLL-
 EES IN THE AREA.—The number of individuals de-
 scribed in subparagraph (B), divided by the total
 number of such individuals for all
 Medicare+Choice plans described in subparagraph
 (C) for that area and year.

“(ii) MONTHLY NON-DRUG BID AMOUNT.—The
 unadjusted non-drug monthly bid amount.

“(B) COUNTING OF INDIVIDUALS.—The Adminis-
 trator shall count, for each Medicare+Choice plan de-
 scribed in subparagraph (C) for an area and year, the
 number of individuals who reside in the area and who
 were enrolled under such plan under this part during
 March of the previous year.

“(C) EXCLUSION OF PLANS NOT OFFERED IN PRE-
 VIOUS YEAR.—For an area and year, the

Medicare+Choice plans described in this subparagraph are plans that are offered in the area and year and were offered in the area in March of the previous year.

“(5) COMPUTATION OF NATIONAL FEE-FOR-SERVICE MARKET SHARE PERCENTAGE.—The Administrator shall determine, for a year, the proportion (in this subsection referred to as the ‘national fee-for-service market share percentage’) of Medicare+Choice eligible individuals who during March of the previous year were not enrolled in a Medicare+Choice plan.

“(6) FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG BID.—For purposes of this part, the term ‘fee-for-service area-specific non-drug bid’ means, for an area and year, the amount described in section 1853(j)(1) for the area and year, except that any reference to a percent of less than 100 percent shall be deemed a reference to 100 percent.”.

(b) APPLICATION OF CHOICE NON-DRUG BENCHMARK IN COMPETITIVE-DEMONSTRATION AREAS.—

(1) IN GENERAL.—Section 1854 is amended—

(A) in subsection (b)(1)(C)(i), as added by section 211(b)(1)(A), by striking “(i) REQUIREMENT.—If” and inserting “(i) REQUIREMENT FOR NON-COMPETITIVE-DEMONSTRATION AREAS.—In the case of a Medicare+Choice payment area that is not a competitive-demonstration area designated under section 1853(k)(1), if”;

(B) in subsection (b)(1)(C), as so added, by inserting after clause (i) the following new clause:

“(ii) REQUIREMENT FOR COMPETITIVE-DEMONSTRATION AREAS.—In the case of a Medicare+Choice payment area that is designated as a competitive-demonstration area under section 1853(k)(1), if there are average per capita monthly savings described in paragraph (4) for a Medicare+Choice plan and year, the Medicare+Choice plan shall provide to the enrollee

a monthly rebate equal to 75 percent of such savings.”;

(C) by adding at the end of subsection (b), as amended by section 211(b)(1), the following new paragraph:

“(4) COMPUTATION OF AVERAGE PER CAPITA MONTHLY SAVINGS FOR COMPETITIVE-DEMONSTRATION AREAS.—For purposes of paragraph (1)(C)(ii), the average per capita monthly savings referred to in such paragraph for a Medicare+Choice plan and year shall be computed in the same manner as the average per capita monthly savings is computed under paragraph (3) except that the reference to the fee-for-service area-specific non-drug benchmark in paragraph (3)(B)(i) (or to the benchmark amount as adjusted under paragraph (3)(C)(i)) is deemed to be a reference to the choice non-drug benchmark amount (or such amount as adjusted in the manner described in paragraph (3)(B)(i)).”; and

(D) in subsection (d), as amended by section 211(d)(4), by inserting “and subsection (b)(1)(D)” after “subsection (b)(1)(C),”.

(2) CONFORMING AMENDMENTS.—

(A) PAYMENT OF PLANS.—Section 1853(a)(1)(A)(ii), as amended by section 211(c)(1), is amended—

(i) in subclause (I), by inserting “(or, in the case of a competitive-demonstration area, the choice non-drug benchmark amount)” after “benchmark amount”; and

(ii) in subclauses (I) and (II), by inserting “(or, in the case of a competitive-demonstration area, described in section 1854(b)(4))” after “section 1854(b)(1)(C)”.

(B) DEFINITION OF MONTHLY BASIC PREMIUM.—Section 1854(b)(2)(A)(ii), as amended by section 211(d)(2), is amended by inserting “(or, in the case of

1 a competitive-demonstration area, the choice non-drug
2 benchmark amount)” after “benchmark amount”.

3 (c) PREMIUM ADJUSTMENT.—Section 1839 (42 U.S.C.
4 1395r) is amended by adding at the end the following new sub-
5 section:

6 “(h)(1) In the case of an individual who resides in a com-
7 petitive-demonstration area designated under section
8 1851(k)(1) and who is not enrolled in a Medicare+Choice plan
9 under part C, the monthly premium otherwise applied under
10 this part (determined without regard to subsections (b) and (f)
11 or any adjustment under this subsection) shall be adjusted as
12 follows: If the fee-for-service area-specific non-drug bid (as de-
13 fined in section 1853(k)(6)) for the Medicare+Choice area in
14 which the individual resides for a month—

15 “(A) does not exceed the choice non-drug benchmark
16 (as determined under section 1853(k)(2)) for such area,
17 the amount of the premium for the individual for the
18 month shall be reduced by an amount equal to 75 percent
19 of the amount by which such benchmark exceeds such fee-
20 for-service bid; or

21 “(B) exceeds such choice non-drug benchmark, the
22 amount of the premium for the individual for the month
23 shall be adjusted to ensure that—

24 “(i) the sum of the amount of the adjusted pre-
25 mium and the choice non-drug benchmark for the area,
26 is equal to

27 “(ii) the sum of the unadjusted premium plus
28 amount of the fee-for-service area-specific non-drug bid
29 for the area.

30 “(2) Nothing in this subsection shall be construed as pre-
31 venting a reduction under paragraph (1)(A) in the premium
32 otherwise applicable under this part to zero or from requiring
33 the provision of a rebate to the extent such premium would
34 otherwise be required to be less than zero.

35 “(3) The adjustment in the premium under this subsection
36 shall be effected in such manner as the Medicare Benefits Ad-
37 ministrator determines appropriate.

“(4) In order to carry out this subsection (insofar as it is effected through the manner of collection of premiums under 1840(a)), the Medicare Benefits Administrator shall transmit to the Commissioner of Social Security—

“(A) at the beginning of each year, the name, social security account number, and the amount of the adjustment (if any) under this subsection for each individual enrolled under this part for each month during the year; and

“(B) periodically throughout the year, information to update the information previously transmitted under this paragraph for the year.”.

(d) CONFORMING AMENDMENT.—Section 1844(c) (42 U.S.C. 1395w(c)) is amended by inserting “and without regard to any premium adjustment effected under section 1839(h)” before the period at the end.

(e) REPORT ON DEMONSTRATION PROGRAM.—Not later than 6 months after the date on which the designation of the 4th competitive-demonstration area under section 1851(k)(1) of the Social Security Act ends, the Medicare Payment Advisory Commission shall submit to Congress a report on the impact of the demonstration program under the amendments made by this section, including such impact on premiums of medicare beneficiaries, savings to the medicare program, and on adverse selection.

(f) EFFECTIVE DATE.—The amendments made by this section shall apply to payments and premiums for periods beginning on or after January 1, 2005.

SEC. 213. CONFORMING AMENDMENTS.

(a) CONFORMING AMENDMENTS RELATING TO BIDS.—

(1) Section 1854 (42 U.S.C. 1395w-24) is amended—

(A) in the heading by inserting “AND BID AMOUNTS” after “PREMIUMS”;

(B) in the heading of subsection (a), by inserting “AND BID AMOUNTS” after “PREMIUMS”; and

(C) in subsection (a)(5)(A), by inserting “paragraphs (2), (3), and (4) of” after “filed under”.

(b) ADDITIONAL CONFORMING AMENDMENTS.—

(1) ANNUAL DETERMINATION AND ANNOUNCEMENT
OF CERTAIN FACTORS.—Section 1853(b) (42 U.S.C.
1395w-23(b)) is amended—

(A) in paragraph (1), by striking “the calendar
year concerned” and all that follows and inserting the
following: “the calendar year concerned with respect to
each Medicare+Choice payment area, the following:

“(A) PRE-COMPETITION INFORMATION.—For
years before 2005, the following:

“(i) MEDICARE+CHOICE CAPITATION
RATES.—The annual Medicare+Choice capitation
rate for each Medicare+Choice payment area for
the year.

“(ii) ADJUSTMENT FACTORS.—The risk and
other factors to be used in adjusting such rates
under subsection (a)(1)(A) for payments for
months in that year.

“(B) COMPETITION INFORMATION.—For years be-
ginning with 2005, the following:

“(i) BENCHMARKS.—The fee-for-service area-
specific non-drug benchmark under section 1853(j)
and, if applicable, the choice non-drug benchmark
under section 1853(k)(2), for the year involved
and, if applicable, the national fee-for-service mar-
ket share percentage.

“(ii) ADJUSTMENT FACTORS.—The adjust-
ment factors applied under section
1853(a)(1)(A)(iii) (relating to demographic adjust-
ment), section 1853(a)(1)(B) (relating to adjust-
ment for end-stage renal disease), and section
1853(a)(3) (relating to health status adjustment).

“(iii) PROJECTED FEE-FOR-SERVICE BID.—In
the case of a competitive area, the projected fee-
for-service area-specific non-drug bid (as deter-
mined under subsection (k)(6)) for the area.

“(iv) INDIVIDUALS.—The number of individ-
uals counted under subsection (k)(4)(B) and en-

rolled in each Medicare+Choice plan in the area.”;

and

(B) in paragraph (3), by striking “in sufficient detail” and all that follows up to the period at the end.

(2) REPEAL OF PROVISIONS RELATING TO ADJUSTED COMMUNITY RATE (ACR).—

(A) IN GENERAL.—Subsections (e) and (f) of section 1854 (42 U.S.C. 1395w–24) are repealed.

(B) CONFORMING AMENDMENT.—Section 1839(a)(2) (42 U.S.C. 1395r(a)(2)) is amended by striking “, and to reflect” and all that follows and inserting a period.

(3) PROSPECTIVE IMPLEMENTATION OF NATIONAL COVERAGE DETERMINATIONS.—Section 1852(a)(5) (42 U.S.C. 1395w–22(a)(5)) is amended to read as follows:

“(5) PROSPECTIVE IMPLEMENTATION OF NATIONAL COVERAGE DETERMINATIONS.—The Secretary shall only implement a national coverage determination that will result in a significant change in the costs to a Medicare+Choice organization in a prospective manner that applies to announcements made under section 1853(b) after the date of the implementation of the determination.”.

(4) PERMITTING GEOGRAPHIC ADJUSTMENT TO CONSOLIDATE MULTIPLE MEDICARE+CHOICE PAYMENT AREAS IN A STATE INTO A SINGLE STATEWIDE MEDICARE+CHOICE PAYMENT AREA.—Section 1853(d)(3) (42 U.S.C. 1395w–23(e)(3)) is amended—

(A) by amending clause (i) of subparagraph (A) to read as follows:

“(i) to a single statewide Medicare+Choice payment area,”; and

(B) by amending subparagraph (B) to read as follows:

“(B) BUDGET NEUTRALITY ADJUSTMENT.—In the case of a State requesting an adjustment under this paragraph, the Medicare Benefits Administrator shall

initially (and annually thereafter) adjust the payment rates otherwise established under this section for Medicare+Choice payment areas in the State in a manner so that the aggregate of the payments under this section in the State shall not exceed the aggregate payments that would have been made under this section for Medicare+Choice payment areas in the State in the absence of the adjustment under this paragraph.”.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to payments and premiums for periods beginning on or after January 1, 2005.

TITLE III—RURAL HEALTH CARE IMPROVEMENTS

SEC. 301. REFERENCE TO FULL MARKET BASKET INCREASE FOR SOLE COMMUNITY HOSPITALS.

For provision eliminating any reduction from full market basket in the update for inpatient hospital services for sole community hospitals, see section 401.

SEC. 302. ENHANCED DISPROPORTIONATE SHARE HOSPITAL (DSH) TREATMENT FOR RURAL HOSPITALS AND URBAN HOSPITALS WITH FEWER THAN 100 BEDS.

(a) BLENDING OF PAYMENT AMOUNTS.—

(1) IN GENERAL.—Section 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is amended by adding at the end the following new clause:

“(xiv)(I) In the case of discharges in a fiscal year beginning on or after October 1, 2002, subject to subclause (II), there shall be substituted for the disproportionate share adjustment percentage otherwise determined under clause (iv) (other than subclause (I)) or under clause (viii), (x), (xi), (xii), or (xiii), the old blend proportion (specified under subclause (III)) of the disproportionate share adjustment percentage otherwise determined under the respective clause and 100 percent minus such old blend proportion of the disproportionate share adjustment percentage determined under clause (vii) (relating to large, urban hospitals).

“(II) Under subclause (I), the disproportionate share adjustment percentage shall not exceed 10 percent for a hospital that is not classified as a rural referral center under subparagraph (C).

“(III) For purposes of subclause (I), the old blend proportion for fiscal year 2003 is 80 percent, for each subsequent year (through 2006) is the old blend proportion under this subclause for the previous year minus 20 percentage points, and for each year beginning with 2007 is 0 percent.”.

(2) CONFORMING AMENDMENTS.—Section 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is amended—

(A) in each of subclauses (II), (III), (IV), (V), and (VI) of clause (iv), by inserting “subject to clause (xiv) and” before “for discharges occurring”;

(B) in clause (viii), by striking “The formula” and inserting “Subject to clause (xiv), the formula”; and

(C) in each of clauses (x), (xi), (xii), and (xiii), by striking “For purposes” and inserting “Subject to clause (xiv), for purposes”.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to discharges occurring on or after October 1, 2002.

SEC. 303. 2-YEAR PHASED-IN INCREASE IN THE STANDARDIZED AMOUNT IN RURAL AND SMALL URBAN AREAS TO ACHIEVE A SINGLE, UNIFORM STANDARDIZED AMOUNT.

Section 1886(d)(3)(A)(iv) (42 U.S.C. 1395ww(d)(3)(A)(iv)) is amended—

(1) by striking “(iv) For discharges” and inserting “(iv)(I) Subject to the succeeding provisions of this clause, for discharges”; and

(2) by adding at the end the following new subclauses:

“(II) For discharges occurring during fiscal year 2003, the average standardized amount for hospitals located other than in a large urban area shall be increased by $\frac{1}{2}$ of the difference between the average standardized amount determined under subclause (I) for hospitals lo-

1 cated in large urban areas for such fiscal year and such
 2 amount determined (without regard to this subclause) for
 3 other hospitals for such fiscal year.

4 “(III) For discharges occurring in a fiscal year begin-
 5 ning with fiscal year 2004, the Secretary shall compute an
 6 average standardized amount for hospitals located in any
 7 area within the United States and within each region equal
 8 to the average standardized amount computed for the pre-
 9 vious fiscal year under this subparagraph for hospitals lo-
 10 cated in a large urban area (or, beginning with fiscal year
 11 2005, for hospitals located in any area) increased by the
 12 applicable percentage increase under subsection
 13 (b)(3)(B)(i).”.

14 **SEC. 304. MORE FREQUENT UPDATE IN WEIGHTS USED**
 15 **IN HOSPITAL MARKET BASKET.**

16 (a) MORE FREQUENT UPDATES IN WEIGHTS.—After re-
 17 vising the weights used in the hospital market basket under
 18 section 1886(b)(3)(B)(iii) of the Social Security Act (42 U.S.C.
 19 1395ww(b)(3)(B)(iii)) to reflect the most current data avail-
 20 able, the Secretary shall establish a frequency for revising such
 21 weights in such market basket to reflect the most current data
 22 available more frequently than once every 5 years.

23 (b) REPORT.—Not later than October 1, 2003, the Sec-
 24 retary shall submit a report to Congress on the frequency es-
 25 tablished under subsection (a), including an explanation of the
 26 reasons for, and options considered, in determining such fre-
 27 quency.

28 **SEC. 305. IMPROVEMENTS TO CRITICAL ACCESS HOS-**
 29 **PITAL PROGRAM.**

30 (a) REINSTATEMENT OF PERIODIC INTERIM PAYMENT
 31 (PIP).—Section 1815(e)(2) (42 U.S.C. 1395g(e)(2)) is
 32 amended—

33 (1) by striking “and” at the end of subparagraph (C);

34 (2) by adding “and” at the end of subparagraph (D);

35 and

36 (3) by inserting after subparagraph (D) the following
 37 new subparagraph:

1 “(E) inpatient critical access hospital services;”.

2 (b) CONDITION FOR APPLICATION OF SPECIAL PHYSICIAN
3 PAYMENT ADJUSTMENT.—Section 1834(g)(2) (42 U.S.C.
4 1395m(g)(2)) is amended by adding after and below subpara-
5 graph (B) the following:

6 “The Secretary may not require, as a condition for apply-
7 ing subparagraph (B) with respect to a critical access hos-
8 pital, that each physician providing professional services in
9 the hospital must assign billing rights with respect to such
10 services, except that such subparagraph shall not apply to
11 those physicians who have not assigned such billing
12 rights.”.

13 (c) FLEXIBILITY IN BED LIMITATION FOR HOSPITALS
14 WITH STRONG SEASONAL CENSUS FLUCTUATIONS.—Section
15 1820 (42 U.S.C. 1395i-4) is amended—

16 (1) in subsection (c)(2)(B)(iii), by inserting “subject
17 to paragraph (3)” after “(iii) provides”;

18 (2) by adding at the end of subsection (c) the fol-
19 lowing new paragraph:

20 “(3) INCREASE IN MAXIMUM NUMBER OF BEDS FOR
21 HOSPITALS WITH STRONG SEASONAL CENSUS FLUCTUA-
22 TIONS.—

23 “(A) IN GENERAL.—In the case of a hospital that
24 demonstrates that it meets the standards established
25 under subparagraph (B), the bed limitations otherwise
26 applicable under paragraph (2)(B)(iii) and subsection
27 (f) shall be increased by 5 beds.

28 “(B) STANDARDS.—The Secretary shall specify
29 standards for determining whether a critical access hos-
30 pital has sufficiently strong seasonal variations in pa-
31 tient admissions to justify the increase in bed limitation
32 provided under subparagraph (A).”; and

33 (3) in subsection (f), by adding at the end the fol-
34 lowing new sentence: “The limitations in numbers of beds
35 under the first sentence are subject to adjustment under
36 subsection (c)(3).”.

(d) 5-YEAR EXTENSION OF THE AUTHORIZATION FOR APPROPRIATIONS FOR GRANT PROGRAM.—Section 1820(j) (42 U.S.C. 1395i–4(j)) is amended by striking “through 2002” and inserting “through 2007”.

(e) EFFECTIVE DATES.—

(1) REINSTATEMENT OF PIP.—The amendments made by subsection (a) shall apply to payments made on or after January 1, 2003.

(2) PHYSICIAN PAYMENT ADJUSTMENT CONDITION.—The amendment made by subsection (b) shall be effective as if included in the enactment of section 403(d) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (113 Stat. 1501A–371).

(3) FLEXIBILITY IN BED LIMITATION.—The amendments made by subsection (c) shall apply to designations made on or after January 1, 2003, but shall not apply to critical access hospitals that were designated as of such date.

SEC. 306. EXTENSION OF TEMPORARY INCREASE FOR HOME HEALTH SERVICES FURNISHED IN A RURAL AREA.

(a) IN GENERAL.—Section 508(a) BIPA (114 Stat. 2763A–533) is amended—

(1) by striking “24-MONTH INCREASE BEGINNING APRIL 1, 2001” and inserting “IN GENERAL”; and

(2) by striking “April 1, 2003” and inserting “January 1, 2005”.

(b) CONFORMING AMENDMENT.—Section 547(e)(2) of BIPA (114 Stat. 2763A–553) is amended by striking “the period beginning on April 1, 2001, and ending on September 30, 2002,” and inserting “a period under such section”.

SEC. 307. REFERENCE TO 10 PERCENT INCREASE IN PAYMENT FOR HOSPICE CARE FURNISHED IN A FRONTIER AREA AND RURAL HOSPICE DEMONSTRATION PROJECT.

For—

(1) provision of 10 percent increase in payment for hospice care furnished in a frontier area, see section 422; and

(2) provision of a rural hospice demonstration project, see section 423.

SEC. 308. REFERENCE TO PRIORITY FOR HOSPITALS LOCATED IN RURAL OR SMALL URBAN AREAS IN REDISTRIBUTION OF UNUSED GRADUATE MEDICAL EDUCATION RESIDENCIES.

For provision providing priority for hospitals located in rural or small urban areas in redistribution of unused graduate medical education residencies, see section 612.

SEC. 309. GAO STUDY OF GEOGRAPHIC DIFFERENCES IN PAYMENTS FOR PHYSICIANS' SERVICES.

(a) STUDY.—The Comptroller General of the United States shall conduct a study of differences in payment amounts under the physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w-4) for physicians' services in different geographic areas. Such study shall include—

(1) an assessment of the validity of the geographic adjustment factors used for each component of the fee schedule;

(2) an evaluation of the measures used for such adjustment, including the frequency of revisions; and

(3) an evaluation of the methods used to determine professional liability insurance costs used in computing the malpractice component, including a review of increases in professional liability insurance premiums and variation in such increases by State and physician specialty and methods used to update the geographic cost of practice index and relative weights for the malpractice component.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under subsection (a). The report shall include recommendations regarding the use of more current data in computing geographic cost of practice indices as well as the use of data directly representative of physicians' costs (rather than proxy measures of such costs).

SEC. 310. PROVIDING SAFE HARBOR FOR CERTAIN COLLABORATIVE EFFORTS THAT BENEFIT MEDICALLY UNDERSERVED POPULATIONS.

(a) IN GENERAL.—Section 1128B(b)(3) (42 U.S.C. 1320a–7(b)(3)) is amended—

(1) in subparagraph (E), by striking “and” after the semicolon at the end;

(2) in subparagraph (F), by striking the period at the end and inserting “; and”; and

(3) by adding at the end the following new subparagraph:

“(G) any remuneration between a public or non-profit private health center entity described under clause (i) or (ii) of section 1905(l)(2)(B) and any individual or entity providing goods, items, services, donations or loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity.”.

(b) RULEMAKING FOR EXCEPTION FOR HEALTH CENTER ENTITY ARRANGEMENTS.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—The Secretary of Health and Human Services (in this subsection referred to as the “Secretary”) shall establish, on an expedited basis, standards relating to the exception described in section 1128B(b)(3)(G) of the Social Security Act, as added by subsection (a), for health center entity arrangements to the antikickback penalties.

(B) FACTORS TO CONSIDER.—The Secretary shall consider the following factors, among others, in establishing standards relating to the exception for health center entity arrangements under subparagraph (A):

(i) Whether the arrangement between the health center entity and the other party results in savings of Federal grant funds or increased revenues to the health center entity.

(ii) Whether the arrangement between the health center entity and the other party expands or enhances a patient's freedom of choice.

(iii) Whether the arrangement between the health center entity and the other party protects a health care professional's independent medical judgment regarding medically appropriate treatment.

The Secretary may also include other standards and criteria that are consistent with the intent of Congress in enacting the exception established under this section.

(2) INTERIM FINAL EFFECT.—No later than 180 days after the date of enactment of this Act, the Secretary shall publish a rule in the Federal Register consistent with the factors under paragraph (1)(B). Such rule shall be effective and final immediately on an interim basis, subject to such change and revision, after public notice and opportunity (for a period of not more than 60 days) for public comment, as is consistent with this subsection.

TITLE IV—PROVISIONS RELATING TO PART A Subtitle A—Inpatient Hospital Services

SEC. 401. REVISION OF ACUTE CARE HOSPITAL PAY- MENT UPDATES.

Subclause (XVIII) of section 1886(b)(3)(B)(i) (42 U.S.C. 1395ww(b)(3)(B)(i)) is amended to read as follows:

“(XVIII) for fiscal year 2003, the market basket percentage increase for sole community hospitals and such increase minus 0.25 percentage points for other hospitals, and”.

**SEC. 402. 2-YEAR INCREASE IN LEVEL OF ADJUSTMENT
FOR INDIRECT COSTS OF MEDICAL EDUCATION (IME).**

Section 1886(d)(5)(B)(ii) (42 U.S.C. 1395ww(d)(5)(B)(ii)) is amended—

- (1) in subclause (VI) by striking “and” at the end;
- (2) by redesignating subclause (VII) as subclause (IX);
- (3) in subclause (VIII) as so redesignated, by striking “2002” and inserting “2004”; and
- (4) by inserting after subclause (VI) the following new subclause:
 - “(VII) during fiscal year 2003, ‘c’ is equal to 1.47;
 - “(VIII) during fiscal year 2004, ‘c’ is equal to 1.45; and”.

SEC. 403. RECOGNITION OF NEW MEDICAL TECHNOLOGIES UNDER INPATIENT HOSPITAL PPS.

(a) IMPROVING TIMELINESS OF DATA COLLECTION.—Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is amended by adding at the end the following new clause:

“(vii) Under the mechanism under this subparagraph, the Secretary shall provide for the addition of new diagnosis and procedure codes in April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) under this subsection until the fiscal year that begins after such date.”.

(b) ELIGIBILITY STANDARD.—

(1) MINIMUM PERIOD FOR RECOGNITION OF NEW TECHNOLOGIES.—Section 1886(d)(5)(K)(vi) (42 U.S.C. 1395ww(d)(5)(K)(vi)) is amended—

- (A) by inserting “(I)” after “(vi)”; and
- (B) by adding at the end the following new subclause:

“(II) Under such criteria, a service or technology shall not be denied treatment as a new service or technology on the basis of the period of time in which the service or technology has been in use if such period ends before the end of the 2-to-3-

1 year period that begins on the effective date of implementation
 2 of a code under ICD-9-CM (or a successor coding method-
 3 ology) that enables the identification of a significant sample of
 4 specific discharges in which the service or technology has been
 5 used.”.

6 (2) ADJUSTMENT OF THRESHOLD.—Section
 7 1886(d)(5)(K)(ii)(I) (42 U.S.C. 1395ww(d)(5)(K)(ii)(I)) is
 8 amended by inserting “(applying a threshold specified by
 9 the Secretary that is the lesser of 50 percent of the na-
 10 tional average standardized amount for operating costs of
 11 inpatient hospital services for all hospitals and all diag-
 12 nosis-related groups or one standard deviation for the diag-
 13 nosis-related group involved)” after “is inadequate”.

14 (3) CRITERION FOR SUBSTANTIAL IMPROVEMENT.—
 15 Section 1886(d)(5)(K)(vi) (42 U.S.C.
 16 1395ww(d)(5)(K)(vi)), as amended by paragraph (1), is
 17 further amended by adding at the end the following sub-
 18 clause:

19 “(III) The Secretary shall by regulation provide for fur-
 20 ther clarification of the criteria applied to determine whether
 21 a new service or technology represents an advance in medical
 22 technology that substantially improves the diagnosis or treat-
 23 ment of beneficiaries. Under such criteria, in determining
 24 whether a new service or technology represents an advance in
 25 medical technology that substantially improves the diagnosis or
 26 treatment of beneficiaries, the Secretary shall deem a service
 27 or technology as meeting such requirement if the service or
 28 technology is a drug or biological that is designated under sec-
 29 tion 506 or 526 of the Federal Food, Drug, and Cosmetic Act,
 30 approved under section 314.510 or 601.41 of title 21, Code of
 31 Federal Regulations, or designated for priority review when the
 32 marketing application for such drug or biological was filed or
 33 is a medical device for which an exemption has been granted
 34 under section 520(m) of such Act, for which priority review has
 35 been provided under section 515(d)(5) of such Act, or is a sub-
 36 stantially equivalent device for which an expedited review is
 37 provided under section 513(f) of such Act.”.

(4) PROCESS FOR PUBLIC INPUT.—Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)), as amended by paragraph (1), is amended—

(A) in clause (i), by adding at the end the following: “Such mechanism shall be modified to meet the requirements of clause (viii).”; and

(B) by adding at the end the following new clause:

“(viii) The mechanism established pursuant to clause (i) shall be adjusted to provide, before publication of a proposed rule, for public input regarding whether a new service or technology not described in the second sentence of clause (vi)(III) represents an advance in medical technology that substantially improves the diagnosis or treatment of beneficiaries as follows:

“(I) The Secretary shall make public and periodically update a list of all the services and technologies for which an application for additional payment under this subparagraph is pending.

“(II) The Secretary shall accept comments, recommendations, and data from the public regarding whether the service or technology represents a substantial improvement.

“(III) The Secretary shall provide for a meeting at which organizations representing hospitals, physicians, medicare beneficiaries, manufacturers, and any other interested party may present comments, recommendations, and data to the clinical staff of the Centers for Medicare & Medicaid Services before publication of a notice of proposed rulemaking regarding whether service or technology represents a substantial improvement.”.

(c) PREFERENCE FOR USE OF DRG ADJUSTMENT.—Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is further amended by adding at the end the following new clause:

“(ix) Before establishing any add-on payment under this subparagraph with respect to a new technology, the Secretary shall seek to identify one or more diagnosis-related groups associated with such technology, based on similar clinical or anatomical characteristics and the cost of the technology. Within

such groups the Secretary shall assign an eligible new technology into a diagnosis-related group where the average costs of care most closely approximate the costs of care of using the new technology. In such case, no add-on payment under this subparagraph shall be made with respect to such new technology and this clause shall not affect the application of paragraph (4)(C)(iii).”.

(d) IMPROVEMENT IN PAYMENT FOR NEW TECHNOLOGY.—Section 1886(d)(5)(K)(ii)(III) (42 U.S.C. 1395ww(d)(5)(K)(ii)(III)) is amended by inserting after “the estimated average cost of such service or technology” the following: “(based on the marginal rate applied to costs under subparagraph (A))”.

(e) EFFECTIVE DATE.—

(1) IN GENERAL.—The Secretary shall implement the amendments made by this section so that they apply to classification for fiscal years beginning with fiscal year 2004.

(2) RECONSIDERATIONS OF APPLICATIONS FOR FISCAL YEAR 2003 THAT ARE DENIED.—In the case of an application for a classification of a medical service or technology as a new medical service or technology under section 1886(d)(5)(K) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)) that was filed for fiscal year 2003 and that is denied—

(A) the Secretary shall automatically reconsider the application as an application for fiscal year 2004 under the amendments made by this section; and

(B) the maximum time period otherwise permitted for such classification of the service or technology shall be extended by 12 months.

SEC. 404. PHASE-IN OF FEDERAL RATE FOR HOSPITALS IN PUERTO RICO.

Section 1886(d)(9) (42 U.S.C. 1395ww(d)(9)) is amended—

(1) in subparagraph (A)—

(A) in clause (i), by striking “for discharges beginning on or after October 1, 1997, 50 percent (and for discharges between October 1, 1987, and September 30, 1997, 75 percent)” and inserting “the applicable Puerto Rico percentage (specified in subparagraph (E))”; and

(B) in clause (ii), by striking “for discharges beginning in a fiscal year beginning on or after October 1, 1997, 50 percent (and for discharges between October 1, 1987, and September 30, 1997, 25 percent)” and inserting “the applicable Federal percentage (specified in subparagraph (E))”; and

(2) by adding at the end the following new subparagraph:

“(E) For purposes of subparagraph (A), for discharges occurring—

“(i) between October 1, 1987, and September 30, 1997, the applicable Puerto Rico percentage is 75 percent and the applicable Federal percentage is 25 percent;

“(ii) on or after October 1, 1997, and before October 1, 2003, the applicable Puerto Rico percentage is 50 percent and the applicable Federal percentage is 50 percent;

“(iii) during fiscal year 2004, the applicable Puerto Rico percentage is 45 percent and the applicable Federal percentage is 55 percent;

“(iv) during fiscal year 2005, the applicable Puerto Rico percentage is 40 percent and the applicable Federal percentage is 60 percent;

“(v) during fiscal year 2006, the applicable Puerto Rico percentage is 35 percent and the applicable Federal percentage is 65 percent;

“(vi) during fiscal year 2007, the applicable Puerto Rico percentage is 30 percent and the applicable Federal percentage is 70 percent; and

“(vii) on or after October 1, 2007, the applicable Puerto Rico percentage is 25 percent and the applicable Federal percentage is 75 percent.”.

SEC. 405. REFERENCE TO PROVISION RELATING TO ENHANCED DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENTS FOR RURAL HOSPITALS AND URBAN HOSPITALS WITH FEWER THAN 100 BEDS.

For provision enhancing disproportionate share hospital (DSH) treatment for rural hospitals and urban hospitals with fewer than 100 beds, see section 302.

SEC. 406. REFERENCE TO PROVISION RELATING TO 2-YEAR PHASED-IN INCREASE IN THE STANDARDIZED AMOUNT IN RURAL AND SMALL URBAN AREAS TO ACHIEVE A SINGLE, UNIFORM STANDARDIZED AMOUNT.

For provision phasing in over a 2-year period an increase in the standardized amount for rural and small urban areas to achieve a single, uniform, standardized amount, see section 303.

SEC. 407. REFERENCE TO PROVISION FOR MORE FREQUENT UPDATES IN THE WEIGHTS USED IN HOSPITAL MARKET BASKET.

For provision providing for more frequent updates in the weights used in hospital market basket, see section 304.

SEC. 408. REFERENCE TO PROVISION MAKING IMPROVEMENTS TO CRITICAL ACCESS HOSPITAL PROGRAM.

For provision providing making improvements to critical access hospital program, see section 305.

Subtitle B—Skilled Nursing Facility Services

SEC. 411. PAYMENT FOR COVERED SKILLED NURSING FACILITY SERVICES.

(a) TEMPORARY INCREASE IN NURSING COMPONENT OF PPS FEDERAL RATE.—Section 312(a) of BIPA is amended by adding at the end the following new sentence: “The Secretary of Health and Human Services shall increase by 8 percent the nursing component of the case-mix adjusted Federal prospective payment rate specified in Tables 3 and 4 of the final rule published in the Federal Register by the Health Care Financing Administration on July 31, 2000 (65 Fed. Reg. 46770) and

as subsequently updated under section 1888(e)(4)(E)(ii) of the Social Security Act (42 U.S.C. 1395yy(e)(4)(E)(ii)), effective for services furnished on or after October 1, 2002, and before October 1, 2005.”.

(b) ADJUSTMENT TO RUGS FOR AIDS RESIDENTS.—

(1) IN GENERAL.—Paragraph (12) of section 1888(e) (42 U.S.C. 1395yy(e)) is amended to read as follows:

“(12) ADJUSTMENT FOR RESIDENTS WITH AIDS.—

“(A) IN GENERAL.—Subject to subparagraph (B), in the case of a resident of a skilled nursing facility who is afflicted with acquired immune deficiency syndrome (AIDS), the per diem amount of payment otherwise applicable shall be increased by 128 percent to reflect increased costs associated with such residents.

“(B) SUNSET.—Subparagraph (A) shall not apply on and after such date as the Secretary certifies that there is an appropriate adjustment in the case mix under paragraph (4)(G)(i) to compensate for the increased costs associated with residents described in such subparagraph.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to services furnished on or after October 1, 2003.

Subtitle C—Hospice

SEC. 421. COVERAGE OF HOSPICE CONSULTATION SERVICES.

(a) COVERAGE OF HOSPICE CONSULTATION SERVICES.—Section 1812(a) (42 U.S.C. 1395d(a)) is amended—

(1) by striking “and” at the end of paragraph (3);

(2) by striking the period at the end of paragraph (4) and inserting “; and”; and

(3) by inserting after paragraph (4) the following new paragraph:

“(5) for individuals who are terminally ill, have not made an election under subsection (d)(1), and have not have previously received services under this paragraph, services that are furnished by a physician who is the med-

1 ical director or an employee of a hospice program and that
2 consist of—

3 “(A) an evaluation of the individual’s need for
4 pain and symptom management;

5 “(B) counseling the individual with respect to end-
6 of-life issues and care options; and

7 “(C) advising the individual regarding advanced
8 care planning.”.

9 (b) PAYMENT.—Section 1814(i) (42 U.S.C. 1395f(i)) is
10 amended by adding at the end the following new paragraph:

11 “(4) The amount paid to a hospice program with respect
12 to the services under section 1812(a)(5) for which payment
13 may be made under this part shall be equal to an amount
14 equivalent to the amount established for an office or other out-
15 patient visit for evaluation and management associated with
16 presenting problems of moderate severity under the fee sched-
17 ule established under section 1848(b), other than the portion
18 of such amount attributable to the practice expense compo-
19 nent.”.

20 (c) CONFORMING AMENDMENT.—Section
21 1861(dd)(2)(A)(i) (42 U.S.C. 1395x(dd)(2)(A)(i)) is amended
22 by inserting before the comma at the end the following: “and
23 services described in section 1812(a)(5)”.

24 (d) EFFECTIVE DATE.—The amendments made by this
25 section shall apply to services provided by a hospice program
26 on or after January 1, 2004.

27 **SEC. 422. 10 PERCENT INCREASE IN PAYMENT FOR HOS-**
28 **PICE CARE FURNISHED IN A FRONTIER**
29 **AREA.**

30 (a) IN GENERAL.—Section 1814(i)(1) (42 U.S.C.
31 1395f(i)(1)) is amended by adding at the end the following new
32 subparagraph:

33 “(D) With respect to hospice care furnished in a frontier
34 area on or after January 1, 2003, and before January 1, 2008,
35 the payment rates otherwise established for such care shall be
36 increased by 10 percent. For purposes of this subparagraph,

1 the term ‘frontier area’ means a county in which the population
2 density is less than 7 persons per square mile.”.

3 (b) REPORT ON COSTS.—Not later than January 1, 2007,
4 the Comptroller General of the United States shall submit to
5 Congress a report on the costs of furnishing hospice care in
6 frontier areas. Such report shall include recommendations re-
7 garding the appropriateness of extending, and modifying, the
8 payment increase provided under the amendment made by sub-
9 section (a).

10 **SEC. 423. RURAL HOSPICE DEMONSTRATION PROJECT.**

11 (a) IN GENERAL.—The Secretary shall conduct a dem-
12 onstration project for the delivery of hospice care to medicare
13 beneficiaries in rural areas. Under the project medicare bene-
14 ficiaries who are unable to receive hospice care in the home for
15 lack of an appropriate caregiver are provided such care in a fa-
16 cility of 20 or fewer beds which offers, within its walls, the full
17 range of services provided by hospice programs under section
18 1861(dd) of the Social Security Act (42 U.S.C. 1395x(dd)).

19 (b) SCOPE OF PROJECT.—The Secretary shall conduct the
20 project under this section with respect to no more than 3 hos-
21 pice programs over a period of not longer than 5 years each.

22 (c) COMPLIANCE WITH CONDITIONS.—Under the dem-
23 onstration project—

24 (1) the hospice program shall comply with otherwise
25 applicable requirements, except that it shall not be required
26 to offer services outside of the home or to meet the require-
27 ments of section 1861(dd)(2)(A)(iii) of the Social Security
28 Act; and

29 (2) payments for hospice care shall be made at the
30 rates otherwise applicable to such care under title XVIII of
31 such Act.

32 The Secretary may require the program to comply with such
33 additional quality assurance standards for its provision of serv-
34 ices in its facility as the Secretary deems appropriate.

35 (d) REPORT.—Upon completion of the project, the Sec-
36 retary shall submit a report to Congress on the project and

1 shall include in the report recommendations regarding exten-
 2 sion of such project to hospice programs serving rural areas.

3 **Subtitle D—Other Provisions**

4 **SEC. 431. DEMONSTRATION PROJECT FOR USE OF RE-** 5 **COVERY AUDIT CONTRACTORS.**

6 (a) IN GENERAL.—The Secretary of Health and Human
 7 Services shall conduct a demonstration project under this sec-
 8 tion (in this section referred to as the “project”) to dem-
 9 onstrate the use of recovery audit contractors under the Medi-
 10 care Integrity Program in identifying and recouping overpay-
 11 ments under the medicare program for services for which pay-
 12 ment is made under part A of title XVIII of the Social Security
 13 Act. Under the project—

14 (1) payment may be made to such a contractor on a
 15 contingent basis;

16 (2) a percentage of the amount recovered may be re-
 17 tained by the Secretary and shall be available to the pro-
 18 gram management account of the Centers for Medicare &
 19 Medicaid Services; and

20 (3) the Secretary shall examine the efficacy of such
 21 use with respect to duplicative payments, accuracy of cod-
 22 ing, and other payment policies in which overpayments
 23 arise.

24 (b) SCOPE AND DURATION.—The project shall cover at
 25 least 2 States and at least 3 contractors and shall last for not
 26 longer than 3 years.

27 (c) WAIVER.—The Secretary of Health and Human Serv-
 28 ices shall waive such provisions of title XVIII of the Social Se-
 29 curity Act as may be necessary to provide for payment for serv-
 30 ices under the project in accordance with subsection (a).

31 (d) QUALIFICATIONS OF CONTRACTORS.—

32 (1) IN GENERAL.—The Secretary shall enter into a re-
 33 covery audit contract under this section with an entity only
 34 if the entity has staff that has knowledge of and experience
 35 with the payment rules and regulations under the medicare
 36 program or the entity has or will contract with another en-
 37 tity that has such knowledgeable and experienced staff.

(2) INELIGIBILITY OF CERTAIN CONTRACTORS.—The Secretary may not enter into a recovery audit contract under this section with an entity to the extent that the entity is a fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h), a carrier under section 1842 of such Act (42 U.S.C. 1395u), or a Medicare Administrative Contractor under section 1874A of such Act, or any other entity that carries out the type of activities with respect to providers of services under part A that would constitute a conflict of interest, as determined by the Secretary.

(3) PREFERENCE FOR ENTITIES WITH DEMONSTRATED PROFICIENCY WITH PRIVATE INSURERS.—In awarding contracts to recovery audit contractors under this section, the Secretary shall give preference to those entities that the Secretary determines have demonstrated proficiency in recovery audits with private insurers or under the medicaid program under title XIX of such Act.

(e) REPORT.—The Secretary of Health and Human Services shall submit to Congress a report on the project not later than 6 months after the date of its completion. Such reports shall include information on the impact of the project on savings to the medicare program and recommendations on the cost-effectiveness of extending or expanding the project.

TITLE V—PROVISIONS RELATING TO PART B

Subtitle A—Physicians’ Services

SEC. 501. REVISION OF UPDATES FOR PHYSICIANS’ SERVICES.

(a) UPDATE FOR 2003 THROUGH 2005.—

(1) IN GENERAL.—Section 1848(d) (42 U.S.C. 1395w-4(d)) is amended by adding at the end the following new paragraphs:

“(5) UPDATE FOR 2003.—The update to the single conversion factor established in paragraph (1)(C) for 2003 is 2 percent.

“(6) SPECIAL RULES FOR UPDATE FOR 2004 AND 2005.—The following rules apply in determining the update adjustment factors under paragraph (4)(B) for 2004 and 2005:

“(A) USE OF 2002 DATA IN DETERMINING ALLOWABLE COSTS.—

“(i) The reference in clause (ii)(I) of such paragraph to April 1, 1996, is deemed to be a reference to January 1, 2002.

“(ii) The allowed expenditures for 2002 is deemed to be equal to the actual expenditures for physicians’ services furnished during 2002, as estimated by the Secretary.

“(B) 1 PERCENTAGE POINT INCREASE IN GDP UNDER SGR.—The annual average percentage growth in real gross domestic product per capita under subsection (f)(2)(C) for each of 2003, 2004, and 2005 is deemed to be increased by 1 percentage point.”.

(2) CONFORMING AMENDMENT.—Paragraph (4)(B) of such section is amended, in the matter before clause (i), by inserting “and paragraph (6)” after “subparagraph (D)”.

(b) USE OF 10-YEAR ROLLING AVERAGE IN COMPUTING GROSS DOMESTIC PRODUCT.—

(1) IN GENERAL.—Section 1848(f)(2)(C) (42 U.S.C. 1395w-4(f)(2)(C)) is amended—

(A) by striking “projected” and inserting “annual average”; and

(B) by striking “from the previous applicable period to the applicable period involved” and inserting “during the 10-year period ending with the applicable period involved”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to computations of the sustainable growth rate for years beginning with 2002.

(c) ELIMINATION OF TRANSITIONAL ADJUSTMENT.—Section 1848(d)(4)(F) (42 U.S.C. 1395w-4(d)(4)(F)) is amended by striking “subparagraph (A)” and all that follows and insert-

ing “subparagraph (A), for each of 2001 and 2002, of –0.2 percent.”

SEC. 502. STUDIES ON ACCESS TO PHYSICIANS’ SERVICES.

(a) GAO STUDY ON BENEFICIARY ACCESS TO PHYSICIANS’ SERVICES.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on access of medicare beneficiaries to physicians’ services under the medicare program. The study shall include—

(A) an assessment of the use by beneficiaries of such services through an analysis of claims submitted by physicians for such services under part B of the medicare program;

(B) an examination of changes in the use by beneficiaries of physicians’ services over time;

(C) an examination of the extent to which physicians are not accepting new medicare beneficiaries as patients.

(2) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1). The report shall include a determination whether—

(A) data from claims submitted by physicians under part B of the medicare program indicate potential access problems for medicare beneficiaries in certain geographic areas; and

(B) access by medicare beneficiaries to physicians’ services may have improved, remained constant, or deteriorated over time.

(b) STUDY AND REPORT ON SUPPLY OF PHYSICIANS.—

(1) STUDY.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct a study on the adequacy of the supply of physicians (including specialists) in the United States and the factors that affect such supply.

(2) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of this section, the Secretary shall submit to Congress a report on the results of the study described in paragraph (1), including any recommendations for legislation.

SEC. 503. MEDPAC REPORT ON PAYMENT FOR PHYSICIANS' SERVICES.

Not later than 1 year after the date of the enactment of this Act, the Medicare Payment Advisory Commission shall submit to Congress a report on the effect of refinements to the practice expense component of payments for physicians' services in the case of services for which there are no physician work relative value units, after the transition to a full resource-based payment system in 2002, under section 1848 of the Social Security Act (42 U.S.C. 1395w-4). Such report shall examine the following matters by physician specialty:

(1) The effect of such refinements on payment for physicians' services.

(2) The interaction of the practice expense component with other components of and adjustments to payment for physicians' services under such section.

(3) The appropriateness of the amount of compensation by reason of such refinements.

(4) The effect of such refinements on access to care by medicare beneficiaries to physicians' services.

(5) The effect of such refinements on physician participation under the medicare program.

Subtitle B—Other Services

SEC. 511. COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES.

(a) IN GENERAL.—Section 1847 (42 U.S.C. 1395w-3) is amended to read as follows:

“COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES

“SEC. 1847. (a) ESTABLISHMENT OF COMPETITIVE ACQUISITION PROGRAMS.—

“(1) IMPLEMENTATION OF PROGRAMS.—

“(A) IN GENERAL.—The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in paragraph (2)) for which payment is made under this part. Such areas may differ for different items and services.

“(B) PHASED-IN IMPLEMENTATION.—The programs shall be phased-in among competitive acquisition areas over a period of not longer than 3 years in a manner so that the competition under the programs occurs in—

“(i) at least $\frac{1}{3}$ of such areas in 2004; and

“(ii) at least $\frac{2}{3}$ of such areas in 2005.

“(C) WAIVER OF CERTAIN PROVISIONS.—In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

“(2) ITEMS AND SERVICES DESCRIBED.—The items and services referred to in paragraph (1) are the following:

“(A) DURABLE MEDICAL EQUIPMENT AND INHALATION DRUGS USED IN CONNECTION WITH DURABLE MEDICAL EQUIPMENT.—Covered items (as defined in section 1834(a)(13)) for which payment is otherwise made under section 1834(a), other than items used in infusion, and inhalation drugs used in conjunction with durable medical equipment.

“(B) OFF-THE-SHELF ORTHOTICS.—Orthotics (described in section 1861(s)(9)) for which payment is otherwise made under section 1834(h) which require minimal self-adjustment for appropriate use and does not require expertise in trimming, bending, molding, assembling, or customizing to fit to the patient.

“(3) EXEMPTION AUTHORITY.—In carrying out the programs under this section, the Secretary may exempt—

“(A) areas that are not competitive due to low population density; and

“(B) items and services for which the application of competitive acquisition is not likely to result in significant savings.

“(b) PROGRAM REQUIREMENTS.—

“(1) IN GENERAL.—The Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under subsection (a) with respect to such items and services.

“(2) CONDITIONS FOR AWARDED CONTRACT.—

“(A) IN GENERAL.—The Secretary may not award a contract to any entity under the competition conducted in an competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:

“(i) The entity meets quality and financial standards specified by the Secretary or developed by accreditation entities or organizations recognized by the Secretary.

“(ii) The total amounts to be paid under the contract (including costs associated with the administration of the contract) are expected to be less than the total amounts that would otherwise be paid.

“(iii) Beneficiary access to a choice of multiple suppliers in the area is maintained.

“(iv) Beneficiary liability is limited to the applicable percentage of contract award price.

“(B) QUALITY STANDARDS.—The quality standards specified under subparagraph (A)(i) shall not be less than the quality standards that would otherwise apply if this section did not apply and shall include consumer services standards. The Secretary shall con-

1 sult with an expert outside advisory panel composed of
 2 an appropriate selection of representatives of physi-
 3 cians, practitioners, and suppliers to review (and advise
 4 the Secretary concerning) such quality standards.

5 “(3) CONTENTS OF CONTRACT.—

6 “(A) IN GENERAL.—A contract entered into with
 7 an entity under the competition conducted pursuant to
 8 paragraph (1) is subject to terms and conditions that
 9 the Secretary may specify.

10 “(B) TERM OF CONTRACTS.—The Secretary shall
 11 rebid contracts under this section not less often than
 12 once every 3 years.

13 “(4) LIMIT ON NUMBER OF CONTRACTORS.—

14 “(A) IN GENERAL.—The Secretary may limit the
 15 number of contractors in a competitive acquisition area
 16 to the number needed to meet projected demand for
 17 items and services covered under the contracts. In
 18 awarding contracts, the Secretary shall take into ac-
 19 count the ability bidding entities to furnish items or
 20 services in sufficient quantities to meet the anticipated
 21 needs of beneficiaries for such items or services in the
 22 geographic area covered under the contract on a timely
 23 basis.

24 “(B) MULTIPLE WINNERS.—The Secretary shall
 25 award contracts to more than one entity submitting a
 26 bid in each area for an item or service.

27 “(5) PARTICIPATING CONTRACTORS.—Payment shall
 28 not be made for items and services described in subsection
 29 (a)(2) furnished by a contractor and for which competition
 30 is conducted under this section unless—

31 “(A) the contractor has submitted a bid for such
 32 items and services under this section; and

33 “(B) the Secretary has awarded a contract to the
 34 contractor for such items and services under this sec-
 35 tion.

36 “(6) AUTHORITY TO CONTRACT FOR EDUCATION, OUT-
 37 REACH AND COMPLAINT SERVICES.—The Secretary may

enter into a contract with an appropriate entity to address complaints from beneficiaries who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such beneficiaries with respect to the program.

“(c) ANNUAL REPORTS.—The Secretary shall submit to Congress an annual management report on the programs under this section. Each such report shall include information on savings, reductions in cost-sharing, access to items and services, and beneficiary satisfaction.

“(d) DEMONSTRATION PROJECT FOR CLINICAL LABORATORY SERVICES.—

“(1) IN GENERAL.—The Secretary shall conduct a demonstration project on the application of competitive acquisition under this section to clinical diagnostic laboratory tests—

“(A) for which payment is otherwise made under section 1833(h) or 1834(d)(1) (relating to colorectal cancer screening tests); and

“(B) which are furnished without a face-to-face encounter between the individual and the hospital or physician ordering the tests.

“(2) TERMS AND CONDITIONS.—Such project shall be under the same conditions as are applicable to items and services described in subsection (a)(2).

“(3) REPORT.—The Secretary shall submit to Congress—

“(A) an initial report on the project not later than December 31, 2004; and

“(B) such progress and final reports on the project after such date as the Secretary determines appropriate.”.

(b) CONTINUATION OF CERTAIN DEMONSTRATION PROJECTS.—Notwithstanding the amendment made by subsection (a), with respect to demonstration projects implemented by the Secretary under section 1847 of the Social Security Act (42 U.S.C. 1395w–3) (relating to the establishment of competi-

tive acquisition areas) that was in effect on the day before the date of the enactment of this Act, each such demonstration project may continue under the same terms and conditions applicable under that section as in effect on that date.

(c) REPORT ON DIFFERENCES IN PAYMENT FOR LABORATORY SERVICES.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report that analyzes differences in reimbursement between public and private payors for clinical diagnostic laboratory services.

SEC. 512. PAYMENT FOR AMBULANCE SERVICES.

(a) PHASE-IN PROVIDING FLOOR USING BLEND OF FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—Section 1834(l) (42 U.S.C. 1395m(l)) is amended—

(1) in paragraph (2)(E), by inserting “consistent with paragraph (10)” after “in an efficient and fair manner”;

(2) by redesignating the paragraph (8) added by section 221(a) of BIPA as paragraph (9); and

(3) by adding at the end the following new paragraph:

“(10) PHASE-IN PROVIDING FLOOR USING BLEND OF FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—In carrying out the phase-in under paragraph (2)(E) for each level of service furnished in a year before January 1, 2007, the portion of the payment amount that is based on the fee schedule shall not be less than the following blended rate of the fee schedule under paragraph (1) and of a regional fee schedule for the region involved:

“(A) For 2003, the blended rate shall be based 20 percent on the fee schedule under paragraph (1) and 80 percent on the regional fee schedule.

“(B) For 2004, the blended rate shall be based 40 percent on the fee schedule under paragraph (1) and 60 percent on the regional fee schedule.

“(C) For 2005, the blended rate shall be based 60 percent on the fee schedule under paragraph (1) and 40 percent on the regional fee schedule.

“(D) For 2006, the blended rate shall be based 80 percent on the fee schedule under paragraph (1) and 20 percent on the regional fee schedule.

For purposes of this paragraph, the Secretary shall establish a regional fee schedule for each of the 9 Census divisions using the methodology (used in establishing the fee schedule under paragraph (1)) to calculate a regional conversion factor and a regional mileage payment rate and using the same payment adjustments and the same relative value units as used in the fee schedule under such paragraph.”.

(b) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG TRIPS.—Section 1834(l), as amended by subsection (a), is further amended by adding at the end the following new paragraph:

“(11) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG TRIPS.—In the case of ground ambulance services furnished on or after January 1, 2003, and before January 1, 2008, regardless of where the transportation originates, the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 50 miles the per mile rate otherwise established shall be increased by $\frac{1}{4}$ of the payment per mile otherwise applicable to such miles.”.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to ambulance services furnished on or after January 1, 2003.

SEC. 513. 1-YEAR EXTENSION OF MORATORIUM ON THERAPY CAPS; PROVISIONS RELATING TO REPORTS.

(a) 1-YEAR EXTENSION OF MORATORIUM ON THERAPY CAPS.—Section 1833(g)(4) (42 U.S.C. 1395l(g)(4)) is amended by striking “and 2002” and inserting “2002 and 2003”.

(b) PROMPT SUBMISSION OF OVERDUE REPORTS ON PAYMENT AND UTILIZATION OF OUTPATIENT THERAPY SERVICES.—Not later than December 31, 2002, the Secretary shall submit to Congress the reports required under section

1 4541(d)(2) of the Balanced Budget Act of 1997 (relating to al-
 2 ternatives to a single annual dollar cap on outpatient therapy)
 3 and under section 221(d) of the Medicare, Medicaid, and
 4 SCHIP Balanced Budget Refinement Act of 1999 (relating to
 5 utilization patterns for outpatient therapy).

6 (c) IDENTIFICATION OF CONDITIONS AND DISEASES JUS-
 7 TIFYING WAIVER OF THERAPY CAP.—

8 (1) STUDY.—The Secretary shall request the Institute
 9 of Medicine of the National Academy of Sciences to identify
 10 conditions or diseases that should justify conducting an as-
 11 sessment of the need to waive the therapy caps under sec-
 12 tion 1833(g)(4) of the Social Security Act (42 U.S.C.
 13 1395l(g)(4)).

14 (2) REPORTS TO CONGRESS.—Not later than July 1,
 15 2003, the Secretary shall submit to Congress a preliminary
 16 report on the conditions and diseases identified under para-
 17 graph (1) and not later than September 1, 2003, a final
 18 report on the conditions and diseases so identified.

19 (d) GAO STUDY OF PATIENT ACCESS TO PHYSICAL
 20 THERAPIST SERVICES.—

21 (1) STUDY.—The Comptroller General of the United
 22 States shall conduct a study on access to physical therapist
 23 services in States authorizing such services without a physi-
 24 cian referral and in States that require such a physician re-
 25 ferral. The study shall—

26 (A) examine the use of and referral patterns for
 27 physical therapist services for patients age 50 and older
 28 in States that authorize such services without a physi-
 29 cian referral and in States that require such a physi-
 30 cian referral;

31 (B) examine the use of and referral patterns for
 32 physical therapist services for patients who are medi-
 33 care beneficiaries; and

34 (C) examine the delivery of physical therapists'
 35 services within the facilities of Department of Defense;
 36 and

(D) analyze the potential impact on medicare beneficiaries and on expenditures under the medicare program of eliminating the need for a physician referral for physical therapist services under the medicare program.

(2) REPORT.—The Comptroller General shall submit to Congress a report on the study conducted under paragraph (1) by not later than 1 year after the date of the enactment of this Act.

SEC. 514. ACCELERATED IMPLEMENTATION OF 20 PERCENT COINSURANCE FOR HOSPITAL OUTPATIENT DEPARTMENT (OPD) SERVICES; OTHER OPD PROVISIONS.

(a) ACCELERATED IMPLEMENTATION OF COINSURANCE REDUCTIONS.—Section 1833(t)(8)(C)(ii) (42 U.S.C. 1395l(t)(8)(C)(ii)) is amended by striking subclauses (III) through (V) and inserting the following:

“(III) For procedures performed in 2004, 45 percent.

“(IV) For procedures performed in 2005, 40 percent.

“(V) For procedures performed in 2006, 2007, 2008 and 2009, 35 percent.

“(VI) For procedures performed in 2010, 30 percent.

“(VII) For procedures performed in 2011, 25 percent.

“(VIII) For procedures performed in 2012 and thereafter, 20 percent.”.

(b) TREATMENT OF TEMPERATURE MONITORED CRYOABLATION.—

(1) IN GENERAL.—Section 1833(t)(6)(A)(ii) (42 U.S.C. 1395l(t)(6)(A)(ii)) is amended by striking “or temperature monitored cryoablation”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) applies to payment for services furnished on or after January 1, 2003.

SEC. 515. COVERAGE OF AN INITIAL PREVENTIVE PHYSICAL EXAMINATION.

(a) COVERAGE.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)), is amended—

(1) in subparagraph (U), by striking “and” at the end;

(2) in subparagraph (V), by inserting “and” at the end; and

(3) by adding at the end the following new subparagraph:

“(W) an initial preventive physical examination (as defined in subsection (ww));”.

(b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

“Initial Preventive Physical Examination

“(ww) The term ‘initial preventive physical examination’ means physicians’ services consisting of a physical examination with the goal of health promotion and disease detection and includes items and services specified by the Secretary in regulations.”.

(c) PAYMENT AS PHYSICIANS’ SERVICES.—Section 1848(j)(3) (42 U.S.C. 1395w-4(j)(3)) by inserting “(2)(W),” after “(2)(S),”.

(d) OTHER CONFORMING AMENDMENTS.—Section 1862(a) (42 U.S.C. 1395y(a)) is amended—

(1) in paragraph (1)—

(A) by striking “and” at the end of subparagraph (H);

(B) by striking the semicolon at the end of subparagraph (I) and inserting “, and”; and

(C) by adding at the end the following new subparagraph:

“(J) in the case of an initial preventive physical examination, which is performed not later than 6 months after the date the individual’s first coverage period begins under part B;” and

(2) in paragraph (7), by striking “or (H)” and inserting “(H), or (J)”.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2004, but only for individuals whose coverage period begins on or after such date.

SEC. 516. RENAL DIALYSIS SERVICES.

(a) REPORT ON DIFFERENCES IN COSTS IN DIFFERENT SETTINGS.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report containing—

(1) an analysis of the differences in costs of providing renal dialysis services under the medicare program in home settings and in facility settings;

(2) an assessment of the percentage of overhead costs in home settings and in facility settings; and

(3) an evaluation of whether the charges for home dialysis supplies and equipment are reasonable and necessary.

(b) RESTORING COMPOSITE RATE EXCEPTIONS FOR PEDIATRIC FACILITIES.—

(1) IN GENERAL.—Section 422(a)(2) of BIPA is amended—

(A) in subparagraph (A), by striking “and (C)” and inserting “, (C), and (D)”;

(B) in subparagraph (B), by striking “In the case” and inserting “Subject to subparagraph (D), in the case”; and

(C) by adding at the end the following new subparagraph:

“(D) INAPPLICABILITY TO PEDIATRIC FACILITIES.—Subparagraphs (A) and (B) shall not apply, as of October 1, 2002, to pediatric facilities that do not have an exception rate described in subparagraph (C) in effect on such date. For purposes of this subparagraph, the term ‘pediatric facility’ means a renal facil-

ity at least 50 percent of whose patients are individuals under 18 years of age.”.

(2) CONFORMING AMENDMENT.—The fourth sentence of section 1881(b)(7) (42 U.S.C. 1395rr(b)(7)) is amended by striking “The Secretary” and inserting “Subject to section 422(a)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, the Secretary”.

(c) INCREASE IN RENAL DIALYSIS COMPOSITE RATE FOR SERVICES FURNISHED IN 2004.—Notwithstanding any other provision of law, with respect to payment under part B of title XVIII of the Social Security Act for renal dialysis services furnished in 2004, the composite payment rate otherwise established under section 1881(b)(7) of such Act (42 U.S.C. 1395rr(b)(7)) shall be increased by 1.2 percent.

TITLE VI—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

SEC. 601. ELIMINATION OF 15 PERCENT REDUCTION IN PAYMENT RATES UNDER THE PROSPECTIVE PAYMENT SYSTEM.

(a) IN GENERAL.—Section 1895(b)(3)(A) (42 U.S.C. 1395fff(b)(3)(A)) is amended to read as follows:

“(A) INITIAL BASIS.—Under such system the Secretary shall provide for computation of a standard prospective payment amount (or amounts) as follows:

“(i) Such amount (or amounts) shall initially be based on the most current audited cost report data available to the Secretary and shall be computed in a manner so that the total amounts payable under the system for fiscal year 2001 shall be equal to the total amount that would have been made if the system had not been in effect and if section 1861(v)(1)(L)(ix) had not been enacted.

“(ii) For fiscal year 2002 and for the first quarter of fiscal year 2003, such amount (or amounts) shall be equal to the amount (or

amounts) determined under this paragraph for the previous fiscal year, updated under subparagraph (B).

“(iii) For 2003, such amount (or amounts) shall be equal to the amount (or amounts) determined under this paragraph for fiscal year 2002, updated under subparagraph (B) for 2003.

“(iv) For 2004 and each subsequent year, such amount (or amounts) shall be equal to the amount (or amounts) determined under this paragraph for the previous year, updated under subparagraph (B).

Each such amount shall be standardized in a manner that eliminates the effect of variations in relative case mix and area wage adjustments among different home health agencies in a budget neutral manner consistent with the case mix and wage level adjustments provided under paragraph (4)(A). Under the system, the Secretary may recognize regional differences or differences based upon whether or not the services or agency are in an urbanized area.”.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect as if included in the amendments made by section 501 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (as enacted into law by section 1(a)(6) of Public Law 106–554).

SEC. 602. ESTABLISHMENT OF REDUCED COPAYMENT FOR A HOME HEALTH SERVICE EPISODE OF CARE FOR CERTAIN BENEFICIARIES.

(a) PART A.—

(1) IN GENERAL.—Section 1813(a) (42 U.S.C. 1395e(a)) is amended by adding at the end the following new paragraph:

“(5)(A)(i) Subject to clause (ii), the amount payable for home health services furnished to the individual under this title for each episode of care beginning in a year (beginning with

2003) shall be reduced by a copayment equal to the copayment amount specified in subparagraph (B)(ii) such year.

“(ii) The copayment under clause (i) shall not apply—

“(I) in the case of an individual who has been determined to be a qualified medicare beneficiary (as defined in section 1905(p)(1)) or otherwise to be entitled to medical assistance under section 1902(a)(10)(A) or 1902(a)(10)(C); and

“(II) in the case of an episode of care which consists of 4 or fewer visits.

“(B)(i) The Secretary shall estimate, before the beginning of each year (beginning with 2003), the national average payment under this title per episode for home health services projected for the year involved.

“(ii) For each year the copayment amount under this clause is equal to 1.5 percent of the national average payment estimated for the year involved under clause (i). Any amount determined under the preceding sentence which is not a multiple of \$5 shall be rounded to the nearest multiple of \$5.

“(iii) There shall be no administrative or judicial review under section 1869, 1878, or otherwise of the estimation of average payment under clause (i).”.

(2) TIMELY IMPLEMENTATION.—Unless the Secretary of Health and Human Services otherwise provides on a timely basis, the copayment amount specified under section 1813(a)(5)(B)(ii) of the Social Security Act (as added by paragraph (1)) for 2003 shall be deemed to be \$40.

(b) CONFORMING PROVISIONS.—

(1) Section 1833(a)(2)(A) (42 U.S.C. 1395l(a)(2)(A)) is amended by inserting “less the copayment amount applicable under section 1813(a)(5)” after “1895”.

(2) Section 1866(a)(2)(A)(i) (42 U.S.C. 1395cc(a)(2)(A)(i)) is amended—

(A) by striking “or coinsurance” and inserting “, coinsurance, or copayment”; and

(B) by striking “or (a)(4)” and inserting “(a)(4), or (a)(5)”.

1 **SEC. 603. UPDATE IN HOME HEALTH SERVICES.**

2 (a) CHANGE TO CALENDAR YEAR UPDATE.—

3 (1) IN GENERAL.—Section 1895(b) (42 U.S.C.
4 1395fff(b)(3)) is amended—

5 (A) in paragraph (3)(B)(i)—

6 (i) by striking “each fiscal year (beginning
7 with fiscal year 2002)” and inserting “fiscal year
8 2002 and for each subsequent year (beginning with
9 2003)”; and

10 (ii) by inserting “or year” after “the fiscal
11 year”;

12 (B) in paragraph (3)(B)(ii)—

13 (i) in subclause (II), by striking “fiscal year”
14 and inserting “year” and by redesignating such
15 subclause as subclause (III); and

16 (ii) in subclause (I), by striking “each of fiscal
17 years 2002 and 2003” and inserting the following:
18 “fiscal year 2002, the home health market basket
19 percentage increase (as defined in clause (iii))
20 minus 1.1 percentage points;

21 “(II) 2003”;

22 (C) in paragraph (3)(B)(iii), by inserting “or
23 year” after “fiscal year” each place it appears;

24 (D) in paragraph (3)(B)(iv)—

25 (i) by inserting “or year” after “fiscal year”
26 each place it appears; and

27 (ii) by inserting “or years” after “fiscal
28 years”; and

29 (E) in paragraph (5), by inserting “or year” after
30 “fiscal year”.

31 (2) TRANSITION RULE.—The standard prospective
32 payment amount (or amounts) under section 1895(b)(3) of
33 the Social Security Act for the calendar quarter beginning
34 on October 1, 2002, shall be such amount (or amounts) for
35 the previous calendar quarter.

(b) CHANGES IN UPDATES FOR 2003, 2004, AND 2005.—
 Section 1895(b)(3)(B)(ii) (42 U.S.C. 1395fff(b)(3)(B)(ii)), as
 amended by subsection (a)(1)(B), is amended—

(1) in subclause (II), by striking “the home health
 market basket percentage increase (as defined in clause
 (iii)) minus 1.1 percentage points” and inserting “2.0 per-
 centage points”;

(2) by striking “or” at the end of subclause (II);

(3) by redesignating subclause (III) as subclause (V);
 and

(4) by inserting after subclause (II) the following new
 subclause:

“(III) 2004, 1.0 percentage points;

“(IV) 2005, the home health market bas-
 ket percentage increase (as defined in clause
 (iii)) minus 0.8 percentage points; or”.

(c) PAYMENT ADJUSTMENT.—

(1) IN GENERAL.—Section 1895(b)(5) (42 U.S.C.
 1395fff(b)(5)) is amended “5 percent” and inserting “3
 percent”.

(2) EFFECTIVE DATE.—The amendment made by
 paragraph (1) shall apply to years beginning with 2003.

**SEC. 604. OASIS TASK FORCE; SUSPENSION OF CERTAIN
 OASIS DATA COLLECTION REQUIREMENTS
 PENDING TASK FORCE SUBMITTAL OF RE-
 PORT.**

(a) ESTABLISHMENT.—The Secretary of Health and
 Human Services shall establish and appoint a task force (to be
 known as the “OASIS Task Force”) to examine the data col-
 lection and reporting requirements under OASIS. For purposes
 of this section, the term “OASIS” means the Outcome and As-
 sessment Information Set required by reason of section 4602(e)
 of Balanced Budget Act of 1997 (42 U.S.C. 1395fff note).

(b) COMPOSITION.—The OASIS Task Force shall be com-
 posed of the following:

(1) Staff of the Centers for Medicare & Medicaid Serv-
 ices with expertise in post-acute care.

1 (2) Representatives of home health agencies.

2 (3) Health care professionals and research and health
3 care quality experts outside the Federal Government with
4 expertise in post-acute care.

5 (4) Advocates for individuals requiring home health
6 services.

7 (c) DUTIES.—

8 (1) REVIEW AND RECOMMENDATIONS.—The OASIS
9 Task Force shall review and make recommendations to the
10 Secretary regarding changes in OASIS to improve and sim-
11 plify data collection for purposes of—

12 (A) assessing the quality of home health services;
13 and

14 (B) providing consistency in classification of pa-
15 tients into home health resource groups (HHRGs) for
16 payment under section 1895 of the Social Security Act
17 (42 U.S.C. 1395fff).

18 (2) SPECIFIC ITEMS.—In conducting the review under
19 paragraph (1), the OASIS Task Force shall specifically
20 examine—

21 (A) the 41 outcome measures currently in use;

22 (B) the timing and frequency of data collection;
23 and

24 (C) the collection of information on comorbidities
25 and clinical indicators.

26 (3) REPORT.—The OASIS Task Force shall submit a
27 report to the Secretary containing its findings and rec-
28 ommendations for changes in OASIS by not later than 18
29 months after the date of the enactment of this Act.

30 (d) SUNSET.—The OASIS Task Force shall terminate 60
31 days after the date on which the report is submitted under sub-
32 section (c)(2).

33 (e) NONAPPLICATION OF FACA.—The provisions of the
34 Federal Advisory Committee Act shall not apply to the OASIS
35 Task Force.

(f) SUSPENSION OF OASIS REQUIREMENT FOR COLLECTION OF DATA ON NON-MEDICARE AND NON-MEDICAID PATIENTS PENDING TASK FORCE REPORT.—

(1) IN GENERAL.—During the period described in paragraph (2), the Secretary of Health and Human Services may not require, under section 4602(e) of the Balanced Budget Act of 1997 or otherwise under OASIS, a home health agency to gather or submit information that relates to an individual who is not eligible for benefits under either title XVIII or title XIX of the Social Security Act.

(2) PERIOD OF SUSPENSION.—The period described in this paragraph—

(A) begins on January 1, 2003, and

(B) ends on the last day of the 2nd month beginning after the date the report is submitted under subsection (c)(2).

SEC. 605. MEDPAC STUDY ON MEDICARE MARGINS OF HOME HEALTH AGENCIES.

(a) STUDY.—The Medicare Payment Advisory Commission shall conduct a study of payment margins of home health agencies under the home health prospective payment system under section 1895 of the Social Security Act (42 U.S.C. 1395fff). Such study shall examine whether systematic differences in payment margins are related to differences in case mix (as measured by home health resource groups (HHRGs)) among such agencies. The study shall use the partial or full-year cost reports filed by home health agencies.

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Commission shall submit to Congress a report on the study under subsection (a).

Subtitle B—Direct Graduate Medical Education

SEC. 611. EXTENSION OF UPDATE LIMITATION ON HIGH COST PROGRAMS.

Section 1886(h)(2)(D)(iv) (42 U.S.C. 1395ww(h)(2)(D)(iv)) is amended—

- 1 (1) in subclause (I)—
- 2 (A) by striking “AND 2002” and inserting
- 3 “THROUGH 2012”;
- 4 (B) by striking “during fiscal year 2001 or fiscal
- 5 year 2002” and inserting “during the period beginning
- 6 with fiscal year 2001 and ending with fiscal year
- 7 2012”; and
- 8 (C) by striking “subject to subclause (III),”;
- 9 (2) by striking subclause (II); and
- 10 (3) in subclause (III)—
- 11 (A) by redesignating such subclause as subclause
- 12 (II); and
- 13 (B) by striking “or (II)”.

14 **SEC. 612. REDISTRIBUTION OF UNUSED RESIDENT POSI-**
 15 **TIONS.**

16 (a) IN GENERAL.—Section 1886(h)(4) (42 U.S.C.
 17 1395ww(h)(4)) is amended—

- 18 (1) in subparagraph (F), by inserting “subject to sub-
- 19 paragraph (I),” after “October 1, 1997,”;
- 20 (2) in subparagraph (H), by inserting “subject to sub-
- 21 paragraph (I),” after “subparagraphs (F) and (G),”; and
- 22 (3) by adding at the end the following new subpara-
- 23 graph:

24 “(I) REDISTRIBUTION OF UNUSED RESIDENT PO-

25 SITIONS.—

26 “(i) REDUCTION IN LIMIT BASED ON UNUSED

27 POSITIONS.—

28 “(I) IN GENERAL.—If a hospital’s resident

29 level (as defined in clause (iii)(I)) is less than

30 the otherwise applicable resident limit (as de-

31 fined in clause (iii)(II)) for each of the ref-

32 erence periods (as defined in subclause (II)),

33 effective for cost reporting periods beginning on

34 or after January 1, 2003, the otherwise appli-

35 cable resident limit shall be reduced by 75 per-

36 cent of the difference between such limit and

the reference resident level specified in subclause (III) (or subclause (IV) if applicable).

“(II) REFERENCE PERIODS DEFINED.—In this clause, the term ‘reference periods’ means, for a hospital, the 3 most recent consecutive cost reporting periods of the hospital for which cost reports have been settled (or, if not, submitted) on or before September 30, 2001.

“(III) REFERENCE RESIDENT LEVEL.—Subject to subclause (IV), the reference resident level specified in this subclause for a hospital is the highest resident level for the hospital during any of the reference periods.

“(IV) ADJUSTMENT PROCESS.—Upon the timely request of a hospital, the Secretary may adjust the reference resident level for a hospital to be the resident level for the hospital for the cost reporting period that includes July 1, 2002.

“(ii) REDISTRIBUTION.—

“(I) IN GENERAL.—The Secretary is authorized to increase the otherwise applicable resident limits for hospitals by an aggregate number estimated by the Secretary that does not exceed the aggregate reduction in such limits attributable to clause (i) (without taking into account any adjustment under subclause (IV) of such clause).

“(II) EFFECTIVE DATE.—No increase under subclause (I) shall be permitted or taken into account for a hospital for any portion of a cost reporting period that occurs before July 1, 2003, or before the date of the hospital’s application for an increase under this clause. No such increase shall be permitted for a hospital unless the hospital has applied to the Secretary for such increase by December 31, 2004.

“(III) CONSIDERATIONS IN REDISTRIBUTION.—In determining for which hospitals the increase in the otherwise applicable resident limit is provided under subclause (I), the Secretary shall take into account the need for such an increase by specialty and location involved, consistent with subclause (IV).

“(IV) PRIORITY FOR RURAL AND SMALL URBAN AREAS.—In determining for which hospitals and residency training programs an increase in the otherwise applicable resident limit is provided under subclause (I), the Secretary shall first distribute the increase to programs of hospitals located in rural areas or in urban areas that are not large urban areas (as defined for purposes of subsection (d)) on a first-come-first-served basis (as determined by the Secretary) based on a demonstration that the hospital will fill the positions made available under this clause and not to exceed an increase of 25 full-time equivalent positions with respect to any hospital.

“(V) APPLICATION OF LOCALITY ADJUSTED NATIONAL AVERAGE PER RESIDENT AMOUNT.—With respect to additional residency positions in a hospital attributable to the increase provided under this clause, notwithstanding any other provision of this subsection, the approved FTE resident amount is deemed to be equal to the locality adjusted national average per resident amount computed under subparagraph (E) for that hospital.

“(VI) CONSTRUCTION.—Nothing in this clause shall be construed as permitting the redistribution of reductions in residency positions attributable to voluntary reduction programs under paragraph (6) or as affecting the ability

of a hospital to establish new medical residency training programs under subparagraph (H).

“(iii) RESIDENT LEVEL AND LIMIT DEFINED.—In this subparagraph:

“(I) RESIDENT LEVEL.—The term ‘resident level’ means, with respect to a hospital, the total number of full-time equivalent residents, before the application of weighting factors (as determined under this paragraph), in the fields of allopathic and osteopathic medicine for the hospital.

“(II) OTHERWISE APPLICABLE RESIDENT LIMIT.—The term ‘otherwise applicable resident limit’ means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) on the resident level for the hospital determined without regard to this subparagraph.”.

(b) NO APPLICATION OF INCREASE TO IME.—Section 1886(d)(5)(B)(v) (42 U.S.C. 1395ww(d)(5)(B)(v)) is amended by adding at the end the following: “The provisions of clause (i) of subparagraph (I) of subsection (h)(4) shall apply with respect to the first sentence of this clause in the same manner as it applies with respect to subparagraph (F) of such subsection, but the provisions of clause (ii) of such subparagraph shall not apply.”.

(c) REPORT ON EXTENSION OF APPLICATIONS UNDER REDISTRIBUTION PROGRAM.—Not later than July 1, 2004, the Secretary shall submit to Congress a report containing recommendations regarding whether to extend the deadline for applications for an increase in resident limits under section 1886(h)(4)(I)(ii)(II) of the Social Security Act (as added by subsection (a)).

Subtitle C—Other Provisions

SEC. 621. MODIFICATIONS TO MEDICARE PAYMENT ADVISORY COMMISSION (MEDPAC).

(a) EXAMINATION OF BUDGET CONSEQUENCES.—Section 1805(b) (42 U.S.C. 1395b–6(b)) is amended by adding at the end the following new paragraph:

“(8) EXAMINATION OF BUDGET CONSEQUENCES.—Before making any recommendations, the Commission shall examine the budget consequences of such recommendations, directly or through consultation with appropriate expert entities.”.

(b) CONSIDERATION OF EFFICIENT PROVISION OF SERVICES.—Section 1805(b)(2)(B)(i) (42 U.S.C. 1395b–6(b)(2)(B)(i)) is amended by inserting “the efficient provision of” after “expenditures for”.

(c) ADDITIONAL REPORTS.—

(1) DATA NEEDS AND SOURCES.—The Medicare Payment Advisory Commission shall conduct a study, and submit a report to Congress by not later than June 1, 2003, on the need for current data, and sources of current data available, to determine the solvency and financial circumstances of hospitals and other medicare providers of services.

(2) USE OF TAX-RELATED RETURNS.—Using return information provided under Form 990 of the Internal Revenue Service, the Commission shall submit to Congress, by not later than June 1, 2003, a report on the following:

(A) Investments and capital financing of hospitals participating under the medicare program and related foundations.

(B) Access to capital financing for private and for not-for-profit hospitals.

SEC. 622. DEMONSTRATION PROJECT FOR DISEASE MANAGEMENT FOR CERTAIN MEDICARE BENEFICIARIES WITH DIABETES.

(a) IN GENERAL.—The Secretary of Health and Human Services shall conduct a demonstration project under this sec-

tion (in this section referred to as the “project”) to demonstrate the impact on costs and health outcomes of applying disease management to certain medicare beneficiaries with diagnosed diabetes. In no case may the number of participants in the project exceed 30,000 at any time.

(b) VOLUNTARY PARTICIPATION.—

(1) ELIGIBILITY.—Medicare beneficiaries are eligible to participate in the project only if—

(a) they are Hispanic, as determined by the Secretary;

(A) they meet specific medical criteria demonstrating the appropriate diagnosis and the advanced nature of their disease;

(B) their physicians approve of participation in the project; and

(C) they are not enrolled in a Medicare+Choice plan.

(2) BENEFITS.—A medicare beneficiary who is enrolled in the project shall be eligible—

(A) for disease management services related to their diabetes; and

(B) for payment for all costs for prescription drugs without regard to whether or not they relate to the diabetes, except that the project may provide for modest cost-sharing with respect to prescription drug coverage.

(c) CONTRACTS WITH DISEASE MANAGEMENT ORGANIZATIONS.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall carry out the project through contracts with up to three disease management organizations. The Secretary shall not enter into such a contract with an organization unless the organization demonstrates that it can produce improved health outcomes and reduce aggregate medicare expenditures consistent with paragraph (2).

(2) CONTRACT PROVISIONS.—Under such contracts—

1 (A) such an organization shall be required to pro-
 2 vide for prescription drug coverage described in sub-
 3 section (b)(2)(B);

4 (B) such an organization shall be paid a fee nego-
 5 tiated and established by the Secretary in a manner so
 6 that (taking into account savings in expenditures under
 7 parts A and B of the medicare program under title
 8 XVIII of the Social Security Act) there will be no net
 9 increase, and to the extent practicable, there will be a
 10 net reduction in expenditures under the medicare pro-
 11 gram as a result of the project; and

12 (C) such an organization shall guarantee, through
 13 an appropriate arrangement with a reinsurance com-
 14 pany or otherwise, the prohibition on net increases in
 15 expenditures described in subparagraph (B).

16 (3) PAYMENTS.—Payments to such organizations shall
 17 be made in appropriate proportion from the Trust Funds
 18 established under title XVIII of the Social Security Act.

19 (4) WORKING GROUP.—The Secretary shall establish
 20 within the Department of Health and Human Services a
 21 working group consisting of employees of the Department
 22 to carry out the following:

23 (A) To oversee the project.

24 (B) To establish policy and criteria for medicare
 25 disease management programs within the Department,
 26 including the establishment of policy and criteria for
 27 such programs.

28 (C) To identify targeted medical conditions and
 29 targeted individuals.

30 (D) To select areas in which such programs are
 31 carried out.

32 (E) To monitor health outcomes under such pro-
 33 grams.

34 (F) To measure the effectiveness of such programs
 35 in meeting any budget neutrality requirements.

1 (G) Otherwise to serve as a central focal point
 2 within the Department for dissemination of information
 3 on medicare disease management programs.

4 (d) APPLICATION OF MEDIGAP PROTECTIONS TO DEM-
 5 ONSTRATION PROJECT ENROLLEES.—(1) Subject to paragraph
 6 (2), the provisions of section 1882(s)(3) (other than clauses (i)
 7 through (iv) of subparagraph (B)) and 1882(s)(4) of the Social
 8 Security Act shall apply to enrollment (and termination of en-
 9 rollment) in the demonstration project under this section, in
 10 the same manner as they apply to enrollment (and termination
 11 of enrollment) with a Medicare+Choice organization in a
 12 Medicare+Choice plan.

13 (2) In applying paragraph (1)—

14 (A) any reference in clause (v) or (vi) of section
 15 1882(s)(3)(B) of such Act to 12 months is deemed a ref-
 16 erence to the period of the demonstration project; and

17 (B) the notification required under section
 18 1882(s)(3)(D) of such Act shall be provided in a manner
 19 specified by the Secretary of Health and Human Services.

20 (e) DURATION.—The project shall last for not longer than
 21 3 years.

22 (f) WAIVER.—The Secretary of Health and Human Serv-
 23 ices shall waive such provisions of title XVIII of the Social Se-
 24 curity Act as may be necessary to provide for payment for serv-
 25 ices under the project in accordance with subsection (c)(3).

26 (g) REPORT.—The Secretary of Health and Human Serv-
 27 ices shall submit to Congress an interim report on the project
 28 not later than 2 years after the date it is first implemented and
 29 a final report on the project not later than 6 months after the
 30 date of its completion. Such reports shall include information
 31 on the impact of the project on costs and health outcomes and
 32 recommendations on the cost-effectiveness of extending or ex-
 33 panding the project.

34 (h) GAO STUDY ON DISEASE MANAGEMENT PRO-
 35 GRAMS.—The Comptroller General of the United States shall
 36 conduct a study that compares disease management programs
 37 under title XVIII of the Social Security Act with such pro-

grams conducted in the private sector, including the prevalence of such programs and programs for case management. The study shall identify the cost-effectiveness of such programs and any savings achieved by such programs. The Comptroller General shall submit a report on such study to Congress by not later than 18 months after the date of the enactment of this Act.

SEC. 623. DEMONSTRATION PROJECT FOR MEDICAL ADULT DAY CARE SERVICES.

(a) ESTABLISHMENT.—Subject to the succeeding provisions of this section, the Secretary of Health and Human Services shall establish a demonstration project (in this section referred to as the “demonstration project”) under which the Secretary shall, as part of a plan of an episode of care for home health services established for a medicare beneficiary, permit a home health agency, directly or under arrangements with a medical adult day care facility, to provide medical adult day care services as a substitute for a portion of home health services that would otherwise be provided in the beneficiary’s home.

(b) PAYMENT.—

(1) IN GENERAL.—The amount of payment for an episode of care for home health services, a portion of which consists of substitute medical adult day care services, under the demonstration project shall be made at a rate equal to 95 percent of the amount that would otherwise apply for such home health services under section 1895 of the Social Security Act (42 u.s.c. 1395fff). In no case may a home health agency, or a medical adult day care facility under arrangements with a home health agency, separately charge a beneficiary for medical adult day care services furnished under the plan of care.

(2) BUDGET NEUTRALITY FOR DEMONSTRATION PROJECT.—Notwithstanding any other provision of law, the Secretary shall provide for an appropriate reduction in the aggregate amount of additional payments made under section 1895 of the Social Security Act (42 U.S.C. 1395fff) to reflect any increase in amounts expended from the Trust

1 Funds as a result of the demonstration project conducted
2 under this section.

3 (c) DEMONSTRATION PROJECT SITES.—The project estab-
4 lished under this section shall be conducted in not more than
5 5 sites in States selected by the Secretary that license or certify
6 providers of services that furnish medical adult day care serv-
7 ices.

8 (d) DURATION.—The Secretary shall conduct the dem-
9 onstration project for a period of 3 years.

10 (e) VOLUNTARY PARTICIPATION.—Participation of medi-
11 care beneficiaries in the demonstration project shall be vol-
12 untary. The total number of such beneficiaries that may par-
13 ticipate in the project at any given time may not exceed
14 15,000.

15 (f) PREFERENCE IN SELECTING AGENCIES.—In selecting
16 home health agencies to participate under the demonstration
17 project, the Secretary shall give preference to those agencies
18 that—

19 (1) are currently licensed or certified to furnish med-
20 ical adult day care services; and

21 (2) have furnished medical adult day care services to
22 medicare beneficiaries for a continuous 2-year period before
23 the beginning of the demonstration project.

24 (g) WAIVER AUTHORITY.—The Secretary may waive such
25 requirements of title XVIII of the Social Security Act as may
26 be necessary for the purposes of carrying out the demonstra-
27 tion project, other than waiving the requirement that an indi-
28 vidual be homebound in order to be eligible for benefits for
29 home health services.

30 (h) EVALUATION AND REPORT.—The Secretary shall con-
31 duct an evaluation of the clinical and cost effectiveness of the
32 demonstration project. Not later 30 months after the com-
33 mencement of the project, the Secretary shall submit to Con-
34 gress a report on the evaluation, and shall include in the report
35 the following:

36 (1) An analysis of the patient outcomes and costs of
37 furnishing care to the medicare beneficiaries participating

1 in the project as compared to such outcomes and costs to
 2 beneficiaries receiving only home health services for the
 3 same health conditions.

4 (2) Such recommendations regarding the extension,
 5 expansion, or termination of the project as the Secretary
 6 determines appropriate.

7 (i) DEFINITIONS.—In this section:

8 (1) HOME HEALTH AGENCY.—The term “home health
 9 agency” has the meaning given such term in section
 10 1861(o) of the Social Security Act (42 U.S.C. 1395x(o)).

11 (2) MEDICAL ADULT DAY CARE FACILITY.—The term
 12 “medical adult day care facility” means a facility that—

13 (A) has been licensed or certified by a State to
 14 furnish medical adult day care services in the State for
 15 a continuous 2-year period;

16 (B) is engaged in providing skilled nursing serv-
 17 ices and other therapeutic services directly or under ar-
 18 rangement with a home health agency;

19 (C) meets such standards established by the Sec-
 20 retary to assure quality of care and such other require-
 21 ments as the Secretary finds necessary in the interest
 22 of the health and safety of individuals who are fur-
 23 nished services in the facility; and

24 (D) provides medical adult day care services.

25 (3) MEDICAL ADULT DAY CARE SERVICES.—The term
 26 “medical adult day care services” means—

27 (A) home health service items and services de-
 28 scribed in paragraphs (1) through (7) of section
 29 1861(m) furnished in a medical adult day care facility;

30 (B) a program of supervised activities furnished in
 31 a group setting in the facility that—

32 (i) meet such criteria as the Secretary deter-
 33 mines appropriate; and

34 (ii) is designed to promote physical and mental
 35 health of the individuals; and

36 (C) such other services as the Secretary may
 37 specify.

(4) MEDICARE BENEFICIARY.—The term “medicare beneficiary” means an individual entitled to benefits under part A of this title, enrolled under part B of this title, or both.

TITLE VII—MEDICARE BENEFITS ADMINISTRATION

SEC. 701. ESTABLISHMENT OF MEDICARE BENEFITS ADMINISTRATION.

(a) IN GENERAL.—Title XVIII (42 U.S.C. 1395 et seq.), as amended by section 105, is amended by inserting after 1806 the following new section:

“MEDICARE BENEFITS ADMINISTRATION

“SEC. 1808. (a) ESTABLISHMENT.—There is established within the Department of Health and Human Services an agency to be known as the Medicare Benefits Administration.

“(b) ADMINISTRATOR; DEPUTY ADMINISTRATOR; CHIEF ACTUARY.—

“(1) ADMINISTRATOR.—

“(A) IN GENERAL.—The Medicare Benefits Administration shall be headed by an administrator to be known as the ‘Medicare Benefits Administrator’ (in this section referred to as the ‘Administrator’) who shall be appointed by the President, by and with the advice and consent of the Senate. The Administrator shall be in direct line of authority to the Secretary.

“(B) COMPENSATION.—The Administrator shall be paid at the rate of basic pay payable for level III of the Executive Schedule under section 5314 of title 5, United States Code.

“(C) TERM OF OFFICE.—The Administrator shall be appointed for a term of 5 years. In any case in which a successor does not take office at the end of an Administrator’s term of office, that Administrator may continue in office until the entry upon office of such a successor. An Administrator appointed to a term of office after the commencement of such term may serve

1 under such appointment only for the remainder of such
2 term.

3 “(D) GENERAL AUTHORITY.—The Administrator
4 shall be responsible for the exercise of all powers and
5 the discharge of all duties of the Administration, and
6 shall have authority and control over all personnel and
7 activities thereof.

8 “(E) RULEMAKING AUTHORITY.—The Adminis-
9 trator may prescribe such rules and regulations as the
10 Administrator determines necessary or appropriate to
11 carry out the functions of the Administration. The reg-
12 ulations prescribed by the Administrator shall be sub-
13 ject to the rulemaking procedures established under
14 section 553 of title 5, United States Code.

15 “(F) AUTHORITY TO ESTABLISH ORGANIZATIONAL
16 UNITS.—The Administrator may establish, alter, con-
17 solidate, or discontinue such organizational units or
18 components within the Administration as the Adminis-
19 trator considers necessary or appropriate, except as
20 specified in this section.

21 “(G) AUTHORITY TO DELEGATE.—The Adminis-
22 trator may assign duties, and delegate, or authorize
23 successive redelegations of, authority to act and to
24 render decisions, to such officers and employees of the
25 Administration as the Administrator may find nec-
26 essary. Within the limitations of such delegations, re-
27 delegations, or assignments, all official acts and deci-
28 sions of such officers and employees shall have the
29 same force and effect as though performed or rendered
30 by the Administrator.

31 “(2) DEPUTY ADMINISTRATOR.—

32 “(A) IN GENERAL.—There shall be a Deputy Ad-
33 ministrator of the Medicare Benefits Administration
34 who shall be appointed by the President, by and with
35 the advice and consent of the Senate.

36 “(B) COMPENSATION.—The Deputy Administrator
37 shall be paid at the rate of basic pay payable for level

1 IV of the Executive Schedule under section 5315 of
2 title 5, United States Code.

3 “(C) TERM OF OFFICE.—The Deputy Adminis-
4 trator shall be appointed for a term of 5 years. In any
5 case in which a successor does not take office at the
6 end of a Deputy Administrator’s term of office, such
7 Deputy Administrator may continue in office until the
8 entry upon office of such a successor. A Deputy Ad-
9 ministrator appointed to a term of office after the com-
10 mencement of such term may serve under such ap-
11 pointment only for the remainder of such term.

12 “(D) DUTIES.—The Deputy Administrator shall
13 perform such duties and exercise such powers as the
14 Administrator shall from time to time assign or dele-
15 gate. The Deputy Administrator shall be Acting Ad-
16 ministrator of the Administration during the absence or
17 disability of the Administrator and, unless the Presi-
18 dent designates another officer of the Government as
19 Acting Administrator, in the event of a vacancy in the
20 office of the Administrator.

21 “(3) CHIEF ACTUARY.—

22 “(A) IN GENERAL.—There is established in the
23 Administration the position of Chief Actuary. The
24 Chief Actuary shall be appointed by, and in direct line
25 of authority to, the Administrator of such Administra-
26 tion. The Chief Actuary shall be appointed from among
27 individuals who have demonstrated, by their education
28 and experience, superior expertise in the actuarial
29 sciences. The Chief Actuary may be removed only for
30 cause.

31 “(B) COMPENSATION.—The Chief Actuary shall
32 be compensated at the highest rate of basic pay for the
33 Senior Executive Service under section 5382(b) of title
34 5, United States Code.

35 “(C) DUTIES.—The Chief Actuary shall exercise
36 such duties as are appropriate for the office of the

1 Chief Actuary and in accordance with professional
2 standards of actuarial independence.

3 “(4) SECRETARIAL COORDINATION OF PROGRAM AD-
4 MINISTRATION.—The Secretary shall ensure appropriate
5 coordination between the Administrator and the Adminis-
6 trator of the Centers for Medicare & Medicaid Services in
7 carrying out the programs under this title.

8 “(c) DUTIES; ADMINISTRATIVE PROVISIONS.—

9 “(1) DUTIES.—

10 “(A) GENERAL DUTIES.—The Administrator shall
11 carry out parts C and D, including—

12 “(i) negotiating, entering into, and enforcing,
13 contracts with plans for the offering of
14 Medicare+Choice plans under part C, including the
15 offering of qualified prescription drug coverage
16 under such plans; and

17 “(ii) negotiating, entering into, and enforcing,
18 contracts with PDP sponsors for the offering of
19 prescription drug plans under part D.

20 “(B) OTHER DUTIES.—The Administrator shall
21 carry out any duty provided for under part C or part
22 D, including demonstration projects carried out in part
23 or in whole under such parts, the programs of all-inclu-
24 sive care for the elderly (PACE program) under section
25 1894, the social health maintenance organization
26 (SHMO) demonstration projects (referred to in section
27 4104(c) of the Balanced Budget Act of 1997), and
28 through a Medicare+Choice project that demonstrates
29 the application of capitation payment rates for frail el-
30 derly medicare beneficiaries through the use of a inter-
31 disciplinary team and through the provision of primary
32 care services to such beneficiaries by means of such a
33 team at the nursing facility involved).

34 “(C) PRESCRIPTION DRUG CARD.—The Adminis-
35 trator shall carry out section 1807 (relating to the
36 medicare prescription drug discount card endorsement
37 program).

1 “(D) NONINTERFERENCE.—In carrying out its
 2 duties with respect to the provision of qualified pre-
 3 scription drug coverage to beneficiaries under this title,
 4 the Administrator may not—

5 “(i) require a particular formulary or institute
 6 a price structure for the reimbursement of covered
 7 outpatient drugs;

8 “(ii) interfere in any way with negotiations be-
 9 tween PDP sponsors and Medicare+Choice organi-
 10 zations and drug manufacturers, wholesalers, or
 11 other suppliers of covered outpatient drugs; and

12 “(iii) otherwise interfere with the competitive
 13 nature of providing such coverage through such
 14 sponsors and organizations.

15 “(E) ANNUAL REPORTS.—Not later March 31 of
 16 each year, the Administrator shall submit to Congress
 17 and the President a report on the administration of
 18 parts C and D during the previous fiscal year.

19 “(2) STAFF.—

20 “(A) IN GENERAL.—The Administrator, with the
 21 approval of the Secretary, may employ, without regard
 22 to chapter 31 of title 5, United States Code, other than
 23 sections 3110 and 3112, such officers and employees as
 24 are necessary to administer the activities to be carried
 25 out through the Medicare Benefits Administration. The
 26 Administrator shall employ staff with appropriate and
 27 necessary expertise in negotiating contracts in the pri-
 28 vate sector.

29 “(B) FLEXIBILITY WITH RESPECT TO COMPENSA-
 30 TION.—

31 “(i) IN GENERAL.—The staff of the Medicare
 32 Benefits Administration shall, subject to clause (ii),
 33 be paid without regard to the provisions of chapter
 34 51 (other than section 5101) and chapter 53 (other
 35 than section 5301) of such title (relating to classi-
 36 fication and schedule pay rates).

“(ii) MAXIMUM RATE.—In no case may the rate of compensation determined under clause (i) exceed the rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

“(C) LIMITATION ON FULL-TIME EQUIVALENT STAFFING FOR CURRENT CMS FUNCTIONS BEING TRANSFERRED.—The Administrator may not employ under this paragraph a number of full-time equivalent employees, to carry out functions that were previously conducted by the Centers for Medicare & Medicaid Services and that are conducted by the Administrator by reason of this section, that exceeds the number of such full-time equivalent employees authorized to be employed by the Centers for Medicare & Medicaid Services to conduct such functions as of the date of the enactment of this Act.

“(3) REDELEGATION OF CERTAIN FUNCTIONS OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES.—

“(A) IN GENERAL.—The Secretary, the Administrator, and the Administrator of the Centers for Medicare & Medicaid Services shall establish an appropriate transition of responsibility in order to redelegate the administration of part C from the Secretary and the Administrator of the Centers for Medicare & Medicaid Services to the Administrator as is appropriate to carry out the purposes of this section.

“(B) TRANSFER OF DATA AND INFORMATION.—The Secretary shall ensure that the Administrator of the Centers for Medicare & Medicaid Services transfers to the Administrator of the Medicare Benefits Administration such information and data in the possession of the Administrator of the Centers for Medicare & Medicaid Services as the Administrator of the Medicare Benefits Administration requires to carry out the duties described in paragraph (1).

“(C) CONSTRUCTION.—Insofar as a responsibility of the Secretary or the Administrator of the Centers for Medicare & Medicaid Services is redelegated to the Administrator under this section, any reference to the Secretary or the Administrator of the Centers for Medicare & Medicaid Services in this title or title XI with respect to such responsibility is deemed to be a reference to the Administrator.

“(d) OFFICE OF BENEFICIARY ASSISTANCE.—

“(1) ESTABLISHMENT.—The Secretary shall establish within the Medicare Benefits Administration an Office of Beneficiary Assistance to coordinate functions relating to outreach and education of medicare beneficiaries under this title, including the functions described in paragraph (2). The Office shall be separate operating division within the Administration.

“(2) DISSEMINATION OF INFORMATION ON BENEFITS AND APPEALS RIGHTS.—

“(A) DISSEMINATION OF BENEFITS INFORMATION.—The Office of Beneficiary Assistance shall disseminate, directly or through contract, to medicare beneficiaries, by mail, by posting on the Internet site of the Medicare Benefits Administration and through a toll-free telephone number, information with respect to the following:

“(i) Benefits, and limitations on payment (including cost-sharing, stop-loss provisions, and formulary restrictions) under parts C and D.

“(ii) Benefits, and limitations on payment under parts A and B, including information on medicare supplemental policies under section 1882. Such information shall be presented in a manner so that medicare beneficiaries may compare benefits under parts A, B, D, and medicare supplemental policies with benefits under Medicare+Choice plans under part C.

“(B) DISSEMINATION OF APPEALS RIGHTS INFORMATION.—The Office of Beneficiary Assistance shall

disseminate to medicare beneficiaries in the manner provided under subparagraph (A) a description of procedural rights (including grievance and appeals procedures) of beneficiaries under the original medicare fee-for-service program under parts A and B, the Medicare+Choice program under part C, and the Voluntary Prescription Drug Benefit Program under part D.

“(e) MEDICARE POLICY ADVISORY BOARD.—

“(1) ESTABLISHMENT.—There is established within the Medicare Benefits Administration the Medicare Policy Advisory Board (in this section referred to the ‘Board’). The Board shall advise, consult with, and make recommendations to the Administrator of the Medicare Benefits Administration with respect to the administration of parts C and D, including the review of payment policies under such parts.

“(2) REPORTS.—

“(A) IN GENERAL.—With respect to matters of the administration of parts C and D, the Board shall submit to Congress and to the Administrator of the Medicare Benefits Administration such reports as the Board determines appropriate. Each such report may contain such recommendations as the Board determines appropriate for legislative or administrative changes to improve the administration of such parts, including the topics described in subparagraph (B). Each such report shall be published in the Federal Register.

“(B) TOPICS DESCRIBED.—Reports required under subparagraph (A) may include the following topics:

“(i) FOSTERING COMPETITION.—Recommendations or proposals to increase competition under parts C and D for services furnished to medicare beneficiaries.

“(ii) EDUCATION AND ENROLLMENT.—Recommendations for the improvement to efforts to

provide medicare beneficiaries information and education on the program under this title, and specifically parts C and D, and the program for enrollment under the title.

“(iii) IMPLEMENTATION OF RISK-ADJUSTMENT.—Evaluation of the implementation under section 1853(a)(3)(C) of the risk adjustment methodology to payment rates under that section to Medicare+Choice organizations offering Medicare+Choice plans that accounts for variations in per capita costs based on health status and other demographic factors.

“(iv) DISEASE MANAGEMENT PROGRAMS.—Recommendations on the incorporation of disease management programs under parts C and D.

“(v) RURAL ACCESS.—Recommendations to improve competition and access to plans under parts C and D in rural areas.

“(C) MAINTAINING INDEPENDENCE OF BOARD.—The Board shall directly submit to Congress reports required under subparagraph (A). No officer or agency of the United States may require the Board to submit to any officer or agency of the United States for approval, comments, or review, prior to the submission to Congress of such reports.

“(3) DUTY OF ADMINISTRATOR OF MEDICARE BENEFITS ADMINISTRATION.—With respect to any report submitted by the Board under paragraph (2)(A), not later than 90 days after the report is submitted, the Administrator of the Medicare Benefits Administration shall submit to Congress and the President an analysis of recommendations made by the Board in such report. Each such analysis shall be published in the Federal Register.

“(4) MEMBERSHIP.—

“(A) APPOINTMENT.—Subject to the succeeding provisions of this paragraph, the Board shall consist of seven members to be appointed as follows:

1 “(i) Three members shall be appointed by the
2 President.

3 “(ii) Two members shall be appointed by the
4 Speaker of the House of Representatives, with the
5 advice of the chairmen and the ranking minority
6 members of the Committees on Ways and Means
7 and on Energy and Commerce of the House of
8 Representatives.

9 “(iii) Two members shall be appointed by the
10 President pro tempore of the Senate with the ad-
11 vice of the chairman and the ranking minority
12 member of the Senate Committee on Finance.

13 “(B) QUALIFICATIONS.—The members shall be
14 chosen on the basis of their integrity, impartiality, and
15 good judgment, and shall be individuals who are, by
16 reason of their education and experience in health care
17 benefits management, exceptionally qualified to perform
18 the duties of members of the Board.

19 “(C) PROHIBITION ON INCLUSION OF FEDERAL
20 EMPLOYEES.—No officer or employee of the United
21 States may serve as a member of the Board.

22 “(5) COMPENSATION.—Members of the Board shall
23 receive, for each day (including travel time) they are en-
24 gaged in the performance of the functions of the board,
25 compensation at rates not to exceed the daily equivalent to
26 the annual rate in effect for level IV of the Executive
27 Schedule under section 5315 of title 5, United States Code.

28 “(6) TERMS OF OFFICE.—

29 “(A) IN GENERAL.—The term of office of mem-
30 bers of the Board shall be 3 years.

31 “(B) TERMS OF INITIAL APPOINTEES.—As des-
32 ignated by the President at the time of appointment,
33 of the members first appointed—

34 “(i) one shall be appointed for a term of 1
35 year;

36 “(ii) three shall be appointed for terms of 2
37 years; and

1 “(iii) three shall be appointed for terms of 3
2 years.

3 “(C) REAPPOINTMENTS.—Any person appointed
4 as a member of the Board may not serve for more than
5 8 years.

6 “(D) VACANCY.—Any member appointed to fill a
7 vacancy occurring before the expiration of the term for
8 which the member’s predecessor was appointed shall be
9 appointed only for the remainder of that term. A mem-
10 ber may serve after the expiration of that member’s
11 term until a successor has taken office. A vacancy in
12 the Board shall be filled in the manner in which the
13 original appointment was made.

14 “(7) CHAIR.—The Chair of the Board shall be elected
15 by the members. The term of office of the Chair shall be
16 3 years.

17 “(8) MEETINGS.—The Board shall meet at the call of
18 the Chair, but in no event less than three times during
19 each fiscal year.

20 “(9) DIRECTOR AND STAFF.—

21 “(A) APPOINTMENT OF DIRECTOR.—The Board
22 shall have a Director who shall be appointed by the
23 Chair.

24 “(B) IN GENERAL.—With the approval of the
25 Board, the Director may appoint, without regard to
26 chapter 31 of title 5, United States Code, such addi-
27 tional personnel as the Director considers appropriate.

28 “(C) FLEXIBILITY WITH RESPECT TO COMPENSA-
29 TION.—

30 “(i) IN GENERAL.—The Director and staff of
31 the Board shall, subject to clause (ii), be paid with-
32 out regard to the provisions of chapter 51 and
33 chapter 53 of such title (relating to classification
34 and schedule pay rates).

35 “(ii) MAXIMUM RATE.—In no case may the
36 rate of compensation determined under clause (i)
37 exceed the rate of basic pay payable for level IV of

the Executive Schedule under section 5315 of title 5, United States Code.

“(D) ASSISTANCE FROM THE ADMINISTRATOR OF THE MEDICARE BENEFITS ADMINISTRATION.—The Administrator of the Medicare Benefits Administration shall make available to the Board such information and other assistance as it may require to carry out its functions.

“(10) CONTRACT AUTHORITY.—The Board may contract with and compensate government and private agencies or persons to carry out its duties under this subsection, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

“(f) FUNDING.—There is authorized to be appropriated, in appropriate part from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund (including the Medicare Prescription Drug Account), such sums as are necessary to carry out this section.”.

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act.

(2) TIMING OF INITIAL APPOINTMENTS.—The Administrator and Deputy Administrator of the Medicare Benefits Administration may not be appointed before March 1, 2003.

(3) DUTIES WITH RESPECT TO ELIGIBILITY DETERMINATIONS AND ENROLLMENT.—The Administrator of the Medicare Benefits Administration shall carry out enrollment under title XVIII of the Social Security Act, make eligibility determinations under such title, and carry out part C of such title for years beginning or after January 1, 2005.

(4) TRANSITION.—Before the date the Administrator of the Medicare Benefits Administration is appointed and assumes responsibilities under this section and section 1807 of the Social Security Act, the Secretary of Health

and Human Services shall provide for the conduct of any responsibilities of such Administrator that are otherwise provided under law.

(c) MISCELLANEOUS ADMINISTRATIVE PROVISIONS.—

(1) ADMINISTRATOR AS MEMBER OF THE BOARD OF TRUSTEES OF THE MEDICARE TRUST FUNDS.—Section 1817(b) and section 1841(b) (42 U.S.C. 1395i(b), 1395t(b)) are each amended by striking “and the Secretary of Health and Human Services, all ex officio,” and inserting “the Secretary of Health and Human Services, and the Administrator of the Medicare Benefits Administration, all ex officio,”.

(2) INCREASE IN GRADE TO EXECUTIVE LEVEL III FOR THE ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES; LEVEL FOR MEDICARE BENEFITS ADMINISTRATOR.—

(A) IN GENERAL.—Section 5314 of title 5, United States Code, by adding at the end the following:

“Administrator of the Centers for Medicare & Medicaid Services .

“Administrator of the Medicare Benefits Administration.”.

(B) CONFORMING AMENDMENT.—Section 5315 of such title is amended by striking “Administrator of the Health Care Financing Administration.”.

(C) EFFECTIVE DATE.—The amendments made by this paragraph take effect on January 1, 2003.

TITLE VIII—REGULATORY REDUCTION AND CONTRACTING REFORM

Subtitle A—Regulatory Reform

SEC. 801. CONSTRUCTION; DEFINITION OF SUPPLIER.

(a) CONSTRUCTION.—Nothing in this title shall be construed—

(1) to compromise or affect existing legal remedies for addressing fraud or abuse, whether it be criminal prosecu-

tion, civil enforcement, or administrative remedies, including under sections 3729 through 3733 of title 31, United States Code (known as the False Claims Act); or

(2) to prevent or impede the Department of Health and Human Services in any way from its ongoing efforts to eliminate waste, fraud, and abuse in the medicare program.

Furthermore, the consolidation of medicare administrative contracting set forth in this Act does not constitute consolidation of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund or reflect any position on that issue.

(b) DEFINITION OF SUPPLIER.—Section 1861 (42 U.S.C. 1395x) is amended by inserting after subsection (c) the following new subsection:

“Supplier

“(d) The term ‘supplier’ means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title.”.

SEC. 802. ISSUANCE OF REGULATIONS.

(a) CONSOLIDATION OF PROMULGATION TO ONCE A MONTH.—

(1) IN GENERAL.—Section 1871 (42 U.S.C. 1395hh) is amended by adding at the end the following new subsection:

“(d)(1) Subject to paragraph (2), the Secretary shall issue proposed or final (including interim final) regulations to carry out this title only on one business day of every month.

“(2) The Secretary may issue a proposed or final regulation described in paragraph (1) on any other day than the day described in paragraph (1) if the Secretary—

“(A) finds that issuance of such regulation on another day is necessary to comply with requirements under law; or

“(B) finds that with respect to that regulation the limitation of issuance on the date described in paragraph (1) is contrary to the public interest.

1 If the Secretary makes a finding under this paragraph, the
 2 Secretary shall include such finding, and brief statement of the
 3 reasons for such finding, in the issuance of such regulation.

4 “(3) The Secretary shall coordinate issuance of new regu-
 5 lations described in paragraph (1) relating to a category of pro-
 6 vider of services or suppliers based on an analysis of the collec-
 7 tive impact of regulatory changes on that category of providers
 8 or suppliers.”.

9 (2) GAO REPORT ON PUBLICATION OF REGULATIONS
 10 ON A QUARTERLY BASIS.—Not later than 3 years after the
 11 date of the enactment of this Act, the Comptroller General
 12 of the United States shall submit to Congress a report on
 13 the feasibility of requiring that regulations described in sec-
 14 tion 1871(d) of the Social Security Act be promulgated on
 15 a quarterly basis rather than on a monthly basis.

16 (3) EFFECTIVE DATE.—The amendment made by
 17 paragraph (1) shall apply to regulations promulgated on or
 18 after the date that is 30 days after the date of the enact-
 19 ment of this Act.

20 (b) REGULAR TIMELINE FOR PUBLICATION OF FINAL
 21 RULES.—

22 (1) IN GENERAL.—Section 1871(a) (42 U.S.C.
 23 1395hh(a)) is amended by adding at the end the following
 24 new paragraph:

25 “(3)(A) The Secretary, in consultation with the Director
 26 of the Office of Management and Budget, shall establish and
 27 publish a regular timeline for the publication of final regula-
 28 tions based on the previous publication of a proposed regulation
 29 or an interim final regulation.

30 “(B) Such timeline may vary among different regulations
 31 based on differences in the complexity of the regulation, the
 32 number and scope of comments received, and other relevant
 33 factors, but shall not be longer than 3 years except under ex-
 34 ceptional circumstances. If the Secretary intends to vary such
 35 timeline with respect to the publication of a final regulation,
 36 the Secretary shall cause to have published in the Federal Reg-
 37 ister notice of the different timeline by not later than the

1 timeline previously established with respect to such regulation.
 2 Such notice shall include a brief explanation of the justification
 3 for such variation.

4 “(C) In the case of interim final regulations, upon the ex-
 5 piration of the regular timeline established under this para-
 6 graph for the publication of a final regulation after opportunity
 7 for public comment, the interim final regulation shall not con-
 8 tinue in effect unless the Secretary publishes (at the end of the
 9 regular timeline and, if applicable, at the end of each suc-
 10 ceeding 1-year period) a notice of continuation of the regulation
 11 that includes an explanation of why the regular timeline (and
 12 any subsequent 1-year extension) was not complied with. If
 13 such a notice is published, the regular timeline (or such
 14 timeline as previously extended under this paragraph) for publi-
 15 cation of the final regulation shall be treated as having been
 16 extended for 1 additional year.

17 “(D) The Secretary shall annually submit to Congress a
 18 report that describes the instances in which the Secretary failed
 19 to publish a final regulation within the applicable regular
 20 timeline under this paragraph and that provides an explanation
 21 for such failures.”.

22 (2) EFFECTIVE DATE.—The amendment made by
 23 paragraph (1) shall take effect on the date of the enact-
 24 ment of this Act. The Secretary shall provide for an appro-
 25 priate transition to take into account the backlog of pre-
 26 viously published interim final regulations.

27 (c) LIMITATIONS ON NEW MATTER IN FINAL REGULA-
 28 TIONS.—

29 (1) IN GENERAL.—Section 1871(a) (42 U.S.C.
 30 1395hh(a)), as amended by subsection (b), is further
 31 amended by adding at the end the following new para-
 32 graph:

33 “(4) If the Secretary publishes notice of proposed rule-
 34 making relating to a regulation (including an interim final reg-
 35 ulation), insofar as such final regulation includes a provision
 36 that is not a logical outgrowth of such notice of proposed rule-
 37 making, that provision shall be treated as a proposed regulation

and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to final regulations published on or after the date of the enactment of this Act.

SEC. 803. COMPLIANCE WITH CHANGES IN REGULATIONS AND POLICIES.

(a) NO RETROACTIVE APPLICATION OF SUBSTANTIVE CHANGES.—

(1) IN GENERAL.—Section 1871 (42 U.S.C. 1395hh), as amended by section 802(a), is amended by adding at the end the following new subsection:

“(e)(1)(A) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this title shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that—

“(i) such retroactive application is necessary to comply with statutory requirements; or

“(ii) failure to apply the change retroactively would be contrary to the public interest.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to substantive changes issued on or after the date of the enactment of this Act.

(b) TIMELINE FOR COMPLIANCE WITH SUBSTANTIVE CHANGES AFTER NOTICE.—

(1) IN GENERAL.—Section 1871(e)(1), as added by subsection (a), is amended by adding at the end the following:

“(B)(i) Except as provided in clause (ii), a substantive change referred to in subparagraph (A) shall not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be, the substantive change.

“(ii) The Secretary may provide for such a substantive change to take effect on a date that precedes the end of the 30-day period under clause (i) if the Secretary finds that waiver of such 30-day period is necessary to comply with statutory requirements or that the application of such 30-day period is contrary to the public interest. If the Secretary provides for an earlier effective date pursuant to this clause, the Secretary shall include in the issuance or publication of the substantive change a finding described in the first sentence, and a brief statement of the reasons for such finding.

“(C) No action shall be taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to compliance actions undertaken on or after the date of the enactment of this Act.

(c) RELIANCE ON GUIDANCE.—

(1) IN GENERAL.—Section 1871(e), as added by subsection (a), is further amended by adding at the end the following new paragraph:

“(2)(A) If—

“(i) a provider of services or supplier follows the written guidance (which may be transmitted electronically) provided by the Secretary or by a medicare contractor (as defined in section 1889(g)) acting within the scope of the contractor’s contract authority, with respect to the furnishing of items or services and submission of a claim for benefits for such items or services with respect to such provider or supplier;

“(ii) the Secretary determines that the provider of services or supplier has accurately presented the circumstances relating to such items, services, and claim to the contractor in writing; and

“(iii) the guidance was in error;

the provider of services or supplier shall not be subject to any sanction (including any penalty or requirement for repayment

of any amount) if the provider of services or supplier reasonably relied on such guidance.

“(B) Subparagraph (A) shall not be construed as preventing the recoupment or repayment (without any additional penalty) relating to an overpayment insofar as the overpayment was solely the result of a clerical or technical operational error.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act but shall not apply to any sanction for which notice was provided on or before the date of the enactment of this Act.

SEC. 804. REPORTS AND STUDIES RELATING TO REGULATORY REFORM.

(a) GAO STUDY ON ADVISORY OPINION AUTHORITY.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to determine the feasibility and appropriateness of establishing in the Secretary authority to provide legally binding advisory opinions on appropriate interpretation and application of regulations to carry out the medicare program under title XVIII of the Social Security Act. Such study shall examine the appropriate timeframe for issuing such advisory opinions, as well as the need for additional staff and funding to provide such opinions.

(2) REPORT.—The Comptroller General shall submit to Congress a report on the study conducted under paragraph (1) by not later than January 1, 2004.

(b) REPORT ON LEGAL AND REGULATORY INCONSISTENCIES.—Section 1871 (42 U.S.C. 1395hh), as amended by section 803(a), is amended by adding at the end the following new subsection:

“(f)(1) Not later than 2 years after the date of the enactment of this subsection, and every 2 years thereafter, the Secretary shall submit to Congress a report with respect to the administration of this title and areas of inconsistency or conflict among the various provisions under law and regulation.

1 “(2) In preparing a report under paragraph (1), the Sec-
2 retary shall collect—

3 “(A) information from individuals entitled to benefits
4 under part A or enrolled under part B, or both, providers
5 of services, and suppliers and from the Medicare Bene-
6 ficiary Ombudsman and the Medicare Provider Ombuds-
7 man with respect to such areas of inconsistency and con-
8 flict; and

9 “(B) information from medicare contractors that
10 tracks the nature of written and telephone inquiries.

11 “(3) A report under paragraph (1) shall include a descrip-
12 tion of efforts by the Secretary to reduce such inconsistency or
13 conflicts, and recommendations for legislation or administrative
14 action that the Secretary determines appropriate to further re-
15 duce such inconsistency or conflicts.”.

16 **Subtitle B—Contracting Reform**

17 **SEC. 811. INCREASED FLEXIBILITY IN MEDICARE AD-** 18 **MINISTRATION.**

19 (a) CONSOLIDATION AND FLEXIBILITY IN MEDICARE AD-
20 MINISTRATION.—

21 (1) IN GENERAL.—Title XVIII is amended by insert-
22 ing after section 1874 the following new section:

23 “CONTRACTS WITH MEDICARE ADMINISTRATIVE CONTRACTORS

24 “SEC. 1874A. (a) AUTHORITY.—

25 “(1) AUTHORITY TO ENTER INTO CONTRACTS.—The
26 Secretary may enter into contracts with any eligible entity
27 to serve as a medicare administrative contractor with re-
28 spect to the performance of any or all of the functions de-
29 scribed in paragraph (4) or parts of those functions (or, to
30 the extent provided in a contract, to secure performance
31 thereof by other entities).

32 “(2) ELIGIBILITY OF ENTITIES.—An entity is eligible
33 to enter into a contract with respect to the performance of
34 a particular function described in paragraph (4) only if—

35 “(A) the entity has demonstrated capability to
36 carry out such function;

“(B) the entity complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement;

“(C) the entity has sufficient assets to financially support the performance of such function; and

“(D) the entity meets such other requirements as the Secretary may impose.

“(3) MEDICARE ADMINISTRATIVE CONTRACTOR DEFINED.—For purposes of this title and title XI—

“(A) IN GENERAL.—The term ‘medicare administrative contractor’ means an agency, organization, or other person with a contract under this section.

“(B) APPROPRIATE MEDICARE ADMINISTRATIVE CONTRACTOR.—With respect to the performance of a particular function in relation to an individual entitled to benefits under part A or enrolled under part B, or both, a specific provider of services or supplier (or class of such providers of services or suppliers), the ‘appropriate’ medicare administrative contractor is the medicare administrative contractor that has a contract under this section with respect to the performance of that function in relation to that individual, provider of services or supplier or class of provider of services or supplier.

“(4) FUNCTIONS DESCRIBED.—The functions referred to in paragraphs (1) and (2) are payment functions, provider services functions, and functions relating to services furnished to individuals entitled to benefits under part A or enrolled under part B, or both, as follows:

“(A) DETERMINATION OF PAYMENT AMOUNTS.—Determining (subject to the provisions of section 1878 and to such review by the Secretary as may be provided for by the contracts) the amount of the payments required pursuant to this title to be made to providers of services, suppliers and individuals.

“(B) MAKING PAYMENTS.—Making payments described in subparagraph (A) (including receipt, dis-

1 bursement, and accounting for funds in making such
2 payments).

3 “(C) BENEFICIARY EDUCATION AND ASSIST-
4 ANCE.—Providing education and outreach to individ-
5 uals entitled to benefits under part A or enrolled under
6 part B, or both, and providing assistance to those indi-
7 viduals with specific issues, concerns or problems.

8 “(D) PROVIDER CONSULTATIVE SERVICES.—Pro-
9 viding consultative services to institutions, agencies,
10 and other persons to enable them to establish and
11 maintain fiscal records necessary for purposes of this
12 title and otherwise to qualify as providers of services or
13 suppliers.

14 “(E) COMMUNICATION WITH PROVIDERS.—Com-
15 municating to providers of services and suppliers any
16 information or instructions furnished to the medicare
17 administrative contractor by the Secretary, and facili-
18 tating communication between such providers and sup-
19 pliers and the Secretary.

20 “(F) PROVIDER EDUCATION AND TECHNICAL AS-
21 SISTANCE.—Performing the functions relating to pro-
22 vider education, training, and technical assistance.

23 “(G) ADDITIONAL FUNCTIONS.—Performing such
24 other functions as are necessary to carry out the pur-
25 poses of this title.

26 “(5) RELATIONSHIP TO MIP CONTRACTS.—

27 “(A) NONDUPLICATION OF DUTIES.—In entering
28 into contracts under this section, the Secretary shall
29 assure that functions of medicare administrative con-
30 tractors in carrying out activities under parts A and B
31 do not duplicate activities carried out under the Medi-
32 care Integrity Program under section 1893. The pre-
33 vious sentence shall not apply with respect to the activ-
34 ity described in section 1893(b)(5) (relating to prior
35 authorization of certain items of durable medical equip-
36 ment under section 1834(a)(15)).

“(B) CONSTRUCTION.—An entity shall not be treated as a medicare administrative contractor merely by reason of having entered into a contract with the Secretary under section 1893.

“(6) APPLICATION OF FEDERAL ACQUISITION REGULATION.—Except to the extent inconsistent with a specific requirement of this title, the Federal Acquisition Regulation applies to contracts under this title.

“(b) CONTRACTING REQUIREMENTS.—

“(1) USE OF COMPETITIVE PROCEDURES.—

“(A) IN GENERAL.—Except as provided in laws with general applicability to Federal acquisition and procurement or in subparagraph (B), the Secretary shall use competitive procedures when entering into contracts with medicare administrative contractors under this section, taking into account performance quality as well as price and other factors.

“(B) RENEWAL OF CONTRACTS.—The Secretary may renew a contract with a medicare administrative contractor under this section from term to term without regard to section 5 of title 41, United States Code, or any other provision of law requiring competition, if the medicare administrative contractor has met or exceeded the performance requirements applicable with respect to the contract and contractor, except that the Secretary shall provide for the application of competitive procedures under such a contract not less frequently than once every five years.

“(C) TRANSFER OF FUNCTIONS.—The Secretary may transfer functions among medicare administrative contractors consistent with the provisions of this paragraph. The Secretary shall ensure that performance quality is considered in such transfers. The Secretary shall provide public notice (whether in the Federal Register or otherwise) of any such transfer (including a description of the functions so transferred, a description of the providers of services and suppliers affected by

1 such transfer, and contact information for the contrac-
 2 tors involved).

3 “(D) INCENTIVES FOR QUALITY.—The Secretary
 4 shall provide incentives for medicare administrative
 5 contractors to provide quality service and to promote
 6 efficiency.

7 “(2) COMPLIANCE WITH REQUIREMENTS.—No con-
 8 tract under this section shall be entered into with any
 9 medicare administrative contractor unless the Secretary
 10 finds that such medicare administrative contractor will per-
 11 form its obligations under the contract efficiently and effec-
 12 tively and will meet such requirements as to financial re-
 13 sponsibility, legal authority, quality of services provided,
 14 and other matters as the Secretary finds pertinent.

15 “(3) PERFORMANCE REQUIREMENTS.—

16 “(A) DEVELOPMENT OF SPECIFIC PERFORMANCE
 17 REQUIREMENTS.—In developing contract performance
 18 requirements, the Secretary shall develop performance
 19 requirements applicable to functions described in sub-
 20 section (a)(4).

21 “(B) CONSULTATION.— In developing such re-
 22 quirements, the Secretary may consult with providers
 23 of services and suppliers, organizations representing in-
 24 dividuals entitled to benefits under part A or enrolled
 25 under part B, or both, and organizations and agencies
 26 performing functions necessary to carry out the pur-
 27 poses of this section with respect to such performance
 28 requirements.

29 “(C) INCLUSION IN CONTRACTS.—All contractor
 30 performance requirements shall be set forth in the con-
 31 tract between the Secretary and the appropriate medi-
 32 care administrative contractor. Such performance
 33 requirements—

34 “(i) shall reflect the performance requirements
 35 developed under subparagraph (A), but may in-
 36 clude additional performance requirements;

1 “(ii) shall be used for evaluating contractor
2 performance under the contract; and

3 “(iii) shall be consistent with the written state-
4 ment of work provided under the contract.

5 “(4) INFORMATION REQUIREMENTS.—The Secretary
6 shall not enter into a contract with a medicare administra-
7 tive contractor under this section unless the contractor
8 agrees—

9 “(A) to furnish to the Secretary such timely infor-
10 mation and reports as the Secretary may find nec-
11 essary in performing his functions under this title; and

12 “(B) to maintain such records and afford such ac-
13 cess thereto as the Secretary finds necessary to assure
14 the correctness and verification of the information and
15 reports under subparagraph (A) and otherwise to carry
16 out the purposes of this title.

17 “(5) SURETY BOND.—A contract with a medicare ad-
18 ministrative contractor under this section may require the
19 medicare administrative contractor, and any of its officers
20 or employees certifying payments or disbursing funds pur-
21 suant to the contract, or otherwise participating in carrying
22 out the contract, to give surety bond to the United States
23 in such amount as the Secretary may deem appropriate.

24 “(c) TERMS AND CONDITIONS.—

25 “(1) IN GENERAL.—A contract with any medicare ad-
26 ministrative contractor under this section may contain such
27 terms and conditions as the Secretary finds necessary or
28 appropriate and may provide for advances of funds to the
29 medicare administrative contractor for the making of pay-
30 ments by it under subsection (a)(4)(B).

31 “(2) PROHIBITION ON MANDATES FOR CERTAIN DATA
32 COLLECTION.—The Secretary may not require, as a condi-
33 tion of entering into, or renewing, a contract under this
34 section, that the medicare administrative contractor match
35 data obtained other than in its activities under this title
36 with data used in the administration of this title for pur-

poses of identifying situations in which the provisions of section 1862(b) may apply.

“(d) LIMITATION ON LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTORS AND CERTAIN OFFICERS.—

“(1) CERTIFYING OFFICER.—No individual designated pursuant to a contract under this section as a certifying officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payments certified by the individual under this section.

“(2) DISBURSING OFFICER.—No disbursing officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payment by such officer under this section if it was based upon an authorization (which meets the applicable requirements for such internal controls established by the Comptroller General) of a certifying officer designated as provided in paragraph (1) of this subsection.

“(3) LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTOR.—No medicare administrative contractor shall be liable to the United States for a payment by a certifying or disbursing officer unless in connection with such payment or in the supervision of or selection of such officer the medicare administrative contractor acted with gross negligence.

“(4) INDEMNIFICATION BY SECRETARY.—

“(A) IN GENERAL.—Subject to subparagraphs (B) and (D), in the case of a medicare administrative contractor (or a person who is a director, officer, or employee of such a contractor or who is engaged by the contractor to participate directly in the claims administration process) who is made a party to any judicial or administrative proceeding arising from or relating directly to the claims administration process under this title, the Secretary may, to the extent the Secretary determines to be appropriate and as specified in the contract with the contractor, indemnify the contractor and such persons.

“(B) CONDITIONS.—The Secretary may not provide indemnification under subparagraph (A) insofar as the liability for such costs arises directly from conduct that is determined by the judicial proceeding or by the Secretary to be criminal in nature, fraudulent, or grossly negligent. If indemnification is provided by the Secretary with respect to a contractor before a determination that such costs arose directly from such conduct, the contractor shall reimburse the Secretary for costs of indemnification.

“(C) SCOPE OF INDEMNIFICATION.—Indemnification by the Secretary under subparagraph (A) may include payment of judgments, settlements (subject to subparagraph (D)), awards, and costs (including reasonable legal expenses).

“(D) WRITTEN APPROVAL FOR SETTLEMENTS.—A contractor or other person described in subparagraph (A) may not propose to negotiate a settlement or compromise of a proceeding described in such subparagraph without the prior written approval of the Secretary to negotiate such settlement or compromise. Any indemnification under subparagraph (A) with respect to amounts paid under a settlement or compromise of a proceeding described in such subparagraph are conditioned upon prior written approval by the Secretary of the final settlement or compromise.

“(E) CONSTRUCTION.—Nothing in this paragraph shall be construed—

“(i) to change any common law immunity that may be available to a medicare administrative contractor or person described in subparagraph (A); or

“(ii) to permit the payment of costs not otherwise allowable, reasonable, or allocable under the Federal Acquisition Regulations.”.

(2) CONSIDERATION OF INCORPORATION OF CURRENT LAW STANDARDS.—In developing contract performance requirements under section 1874A(b) of the Social Security

Act, as inserted by paragraph (1), the Secretary shall consider inclusion of the performance standards described in sections 1816(f)(2) of such Act (relating to timely processing of reconsiderations and applications for exemptions) and section 1842(b)(2)(B) of such Act (relating to timely review of determinations and fair hearing requests), as such sections were in effect before the date of the enactment of this Act.

(b) CONFORMING AMENDMENTS TO SECTION 1816 (RELATING TO FISCAL INTERMEDIARIES).—Section 1816 (42 U.S.C. 1395h) is amended as follows:

(1) The heading is amended to read as follows:
“PROVISIONS RELATING TO THE ADMINISTRATION OF PART A”.

(2) Subsection (a) is amended to read as follows:
“(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.”.

(3) Subsection (b) is repealed.

(4) Subsection (c) is amended—

(A) by striking paragraph (1); and

(B) in each of paragraphs (2)(A) and (3)(A), by striking “agreement under this section” and inserting “contract under section 1874A that provides for making payments under this part”.

(5) Subsections (d) through (i) are repealed.

(6) Subsections (j) and (k) are each amended—

(A) by striking “An agreement with an agency or organization under this section” and inserting “A contract with a medicare administrative contractor under section 1874A with respect to the administration of this part”; and

(B) by striking “such agency or organization” and inserting “such medicare administrative contractor” each place it appears.

(7) Subsection (l) is repealed.

(c) CONFORMING AMENDMENTS TO SECTION 1842 (RELATING TO CARRIERS).—Section 1842 (42 U.S.C. 1395u) is amended as follows:

(1) The heading is amended to read as follows:
 “PROVISIONS RELATING TO THE ADMINISTRATION OF PART B”.

(2) Subsection (a) is amended to read as follows:

“(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.”.

(3) Subsection (b) is amended—

(A) by striking paragraph (1);

(B) in paragraph (2)—

(i) by striking subparagraphs (A) and (B);

(ii) in subparagraph (C), by striking “carriers” and inserting “medicare administrative contractors”; and

(iii) by striking subparagraphs (D) and (E);

(C) in paragraph (3)—

(i) in the matter before subparagraph (A), by striking “Each such contract shall provide that the carrier” and inserting “The Secretary”;

(ii) by striking “will” the first place it appears in each of subparagraphs (A), (B), (F), (G), (H), and (L) and inserting “shall”;

(iii) in subparagraph (B), in the matter before clause (i), by striking “to the policyholders and subscribers of the carrier” and inserting “to the policyholders and subscribers of the medicare administrative contractor”;

(iv) by striking subparagraphs (C), (D), and (E);

(v) in subparagraph (H)—

(I) by striking “if it makes determinations or payments with respect to physicians’ services,”; and

(II) by striking “carrier” and inserting “medicare administrative contractor”;

- 1 (vi) by striking subparagraph (I);
- 2 (vii) in subparagraph (L), by striking the
- 3 semicolon and inserting a period;
- 4 (viii) in the first sentence, after subparagraph
- 5 (L), by striking “and shall contain” and all that
- 6 follows through the period; and
- 7 (ix) in the seventh sentence, by inserting
- 8 “medicare administrative contractor,” after “car-
- 9 rier,”; and
- 10 (D) by striking paragraph (5);
- 11 (E) in paragraph (6)(D)(iv), by striking “carrier”
- 12 and inserting “medicare administrative contractor”;
- 13 and
- 14 (F) in paragraph (7), by striking “the carrier”
- 15 and inserting “the Secretary” each place it appears.
- 16 (4) Subsection (c) is amended—
- 17 (A) by striking paragraph (1);
- 18 (B) in paragraph (2), by striking “contract under
- 19 this section which provides for the disbursement of
- 20 funds, as described in subsection (a)(1)(B),” and in-
- 21 serting “contract under section 1874A that provides for
- 22 making payments under this part”;
- 23 (C) in paragraph (3)(A), by striking “subsection
- 24 (a)(1)(B)” and inserting “section 1874A(a)(3)(B)”;
- 25 (D) in paragraph (4), by striking “carrier” and in-
- 26 serting “medicare administrative contractor”; and
- 27 (E) by striking paragraphs (5) and (6).
- 28 (5) Subsections (d), (e), and (f) are repealed.
- 29 (6) Subsection (g) is amended by striking “carrier or
- 30 carriers” and inserting “medicare administrative contractor
- 31 or contractors”.
- 32 (7) Subsection (h) is amended—
- 33 (A) in paragraph (2)—
- 34 (i) by striking “Each carrier having an agree-
- 35 ment with the Secretary under subsection (a)” and
- 36 inserting “The Secretary”; and

(ii) by striking “Each such carrier” and inserting “The Secretary”;

(B) in paragraph (3)(A)—

(i) by striking “a carrier having an agreement with the Secretary under subsection (a)” and inserting “medicare administrative contractor having a contract under section 1874A that provides for making payments under this part”; and

(ii) by striking “such carrier” and inserting “such contractor”;

(C) in paragraph (3)(B)—

(i) by striking “a carrier” and inserting “a medicare administrative contractor” each place it appears; and

(ii) by striking “the carrier” and inserting “the contractor” each place it appears; and

(D) in paragraphs (5)(A) and (5)(B)(iii), by striking “carriers” and inserting “medicare administrative contractors” each place it appears.

(8) Subsection (l) is amended—

(A) in paragraph (1)(A)(iii), by striking “carrier” and inserting “medicare administrative contractor”; and

(B) in paragraph (2), by striking “carrier” and inserting “medicare administrative contractor”.

(9) Subsection (p)(3)(A) is amended by striking “carrier” and inserting “medicare administrative contractor”.

(10) Subsection (q)(1)(A) is amended by striking “carrier”.

(d) EFFECTIVE DATE; TRANSITION RULE.—

(1) EFFECTIVE DATE.—

(A) IN GENERAL.—Except as otherwise provided in this subsection, the amendments made by this section shall take effect on October 1, 2004, and the Secretary is authorized to take such steps before such date as may be necessary to implement such amendments on a timely basis.

(B) CONSTRUCTION FOR CURRENT CONTRACTS.—

Such amendments shall not apply to contracts in effect before the date specified under subparagraph (A) that continue to retain the terms and conditions in effect on such date (except as otherwise provided under this Act, other than under this section) until such date as the contract is let out for competitive bidding under such amendments.

(C) DEADLINE FOR COMPETITIVE BIDDING.—The

Secretary shall provide for the letting by competitive bidding of all contracts for functions of medicare administrative contractors for annual contract periods that begin on or after October 1, 2009.

(D) WAIVER OF PROVIDER NOMINATION PROVI-

SIONS DURING TRANSITION.—During the period beginning on the date of the enactment of this Act and before the date specified under subparagraph (A), the Secretary may enter into new agreements under section 1816 of the Social Security Act (42 U.S.C. 1395h) without regard to any of the provider nomination provisions of such section.

(2) GENERAL TRANSITION RULES.—The Secretary

shall take such steps, consistent with paragraph (1)(B) and (1)(C), as are necessary to provide for an appropriate transition from contracts under section 1816 and section 1842 of the Social Security Act (42 U.S.C. 1395h, 1395u) to contracts under section 1874A, as added by subsection (a)(1).

(3) AUTHORIZING CONTINUATION OF MIP FUNCTIONS

UNDER CURRENT CONTRACTS AND AGREEMENTS AND UNDER ROLLOVER CONTRACTS.—The provisions contained in the exception in section 1893(d)(2) of the Social Security Act (42 U.S.C. 1395ddd(d)(2)) shall continue to apply notwithstanding the amendments made by this section, and any reference in such provisions to an agreement or contract shall be deemed to include a contract under section

1874A of such Act, as inserted by subsection (a)(1), that continues the activities referred to in such provisions.

(e) REFERENCES.—On and after the effective date provided under subsection (d)(1), any reference to a fiscal intermediary or carrier under title XI or XVIII of the Social Security Act (or any regulation, manual instruction, interpretative rule, statement of policy, or guideline issued to carry out such titles) shall be deemed a reference to an appropriate medicare administrative contractor (as provided under section 1874A of the Social Security Act).

(f) REPORTS ON IMPLEMENTATION.—

(1) PLAN FOR IMPLEMENTATION.—By not later than October 1, 2003, the Secretary shall submit a report to Congress and the Comptroller General of the United States that describes the plan for implementation of the amendments made by this section. The Comptroller General shall conduct an evaluation of such plan and shall submit to Congress, not later than 6 months after the date the report is received, a report on such evaluation and shall include in such report such recommendations as the Comptroller General deems appropriate.

(2) STATUS OF IMPLEMENTATION.—The Secretary shall submit a report to Congress not later than October 1, 2007, that describes the status of implementation of such amendments and that includes a description of the following:

(A) The number of contracts that have been competitively bid as of such date.

(B) The distribution of functions among contracts and contractors.

(C) A timeline for complete transition to full competition.

(D) A detailed description of how the Secretary has modified oversight and management of medicare contractors to adapt to full competition.

**SEC. 812. REQUIREMENTS FOR INFORMATION SECURITY
FOR MEDICARE ADMINISTRATIVE CONTRAC-
TORS.**

(a) IN GENERAL.—Section 1874A, as added by section 811(a)(1), is amended by adding at the end the following new subsection:

“(e) REQUIREMENTS FOR INFORMATION SECURITY.—

“(1) DEVELOPMENT OF INFORMATION SECURITY PROGRAM.—A medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall implement a contractor-wide information security program to provide information security for the operation and assets of the contractor with respect to such functions under this title. An information security program under this paragraph shall meet the requirements for information security programs imposed on Federal agencies under section 3534(b)(2) of title 44, United States Code (other than requirements under subparagraphs (B)(ii), (F)(iii), and (F)(iv) of such section).

“(2) INDEPENDENT AUDITS.—

“(A) PERFORMANCE OF ANNUAL EVALUATIONS.—

Each year a medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall undergo an evaluation of the information security of the contractor with respect to such functions under this title. The evaluation shall—

“(i) be performed by an entity that meets such requirements for independence as the Inspector General of the Department of Health and Human Services may establish; and

“(ii) test the effectiveness of information security control techniques for an appropriate subset of the contractor’s information systems (as defined in section 3502(8) of title 44, United States Code) re-

1 relating to such functions under this title and an as-
 2 sessment of compliance with the requirements of
 3 this subsection and related information security
 4 policies, procedures, standards and guidelines.

5 “(B) DEADLINE FOR INITIAL EVALUATION.—

6 “(i) NEW CONTRACTORS.—In the case of a
 7 medicare administrative contractor covered by this
 8 subsection that has not previously performed the
 9 functions referred to in subparagraphs (A) and (B)
 10 of subsection (a)(4) (relating to determining and
 11 making payments) as a fiscal intermediary or car-
 12 rier under section 1816 or 1842, the first inde-
 13 pendent evaluation conducted pursuant subpara-
 14 graph (A) shall be completed prior to commencing
 15 such functions.

16 “(ii) OTHER CONTRACTORS.—In the case of a
 17 medicare administrative contractor covered by this
 18 subsection that is not described in clause (i), the
 19 first independent evaluation conducted pursuant
 20 subparagraph (A) shall be completed within 1 year
 21 after the date the contractor commences functions
 22 referred to in clause (i) under this section.

23 “(C) REPORTS ON EVALUATIONS.—

24 “(i) TO THE INSPECTOR GENERAL.—The re-
 25 sults of independent evaluations under subpara-
 26 graph (A) shall be submitted promptly to the In-
 27 spector General of the Department of Health and
 28 Human Services.

29 “(ii) TO CONGRESS.—The Inspector General
 30 of Department of Health and Human Services shall
 31 submit to Congress annual reports on the results of
 32 such evaluations.”.

33 (b) APPLICATION OF REQUIREMENTS TO FISCAL INTER-
 34 MEDIARIES AND CARRIERS.—

35 (1) IN GENERAL.—The provisions of section
 36 1874A(e)(2) of the Social Security Act (other than sub-
 37 paragraph (B)), as added by subsection (a), shall apply to

each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(2) DEADLINE FOR INITIAL EVALUATION.—In the case of such a fiscal intermediary or carrier with an agreement or contract under such respective section in effect as of the date of the enactment of this Act, the first evaluation under section 1874A(e)(2)(A) of the Social Security Act (as added by subsection (a)), pursuant to paragraph (1), shall be completed (and a report on the evaluation submitted to the Secretary) by not later than 1 year after such date.

Subtitle C—Education and Outreach

SEC. 821. PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.

(a) COORDINATION OF EDUCATION FUNDING.—

(1) IN GENERAL.—The Social Security Act is amended by inserting after section 1888 the following new section:
“PROVIDER EDUCATION AND TECHNICAL ASSISTANCE

“SEC. 1889. (a) COORDINATION OF EDUCATION FUNDING.—The Secretary shall coordinate the educational activities provided through medicare contractors (as defined in subsection (g), including under section 1893) in order to maximize the effectiveness of Federal education efforts for providers of services and suppliers.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act.

(3) REPORT.—Not later than October 1, 2003, the Secretary shall submit to Congress a report that includes a description and evaluation of the steps taken to coordinate the funding of provider education under section 1889(a) of the Social Security Act, as added by paragraph (1).

(b) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE.—

(1) IN GENERAL.—Section 1874A, as added by section 811(a)(1) and as amended by section 812(a), is amended by adding at the end the following new subsection:

“(f) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE IN PROVIDER EDUCATION AND OUTREACH.—In order to give medicare administrative contractors an incentive to implement effective education and outreach programs for providers of services and suppliers, the Secretary shall develop and implement a methodology to measure the specific claims payment error rates of such contractors in the processing or reviewing of medicare claims.”.

(2) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(f) of the Social Security Act, as added by paragraph (1), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(3) GAO REPORT ON ADEQUACY OF METHODOLOGY.—Not later than October 1, 2003, the Comptroller General of the United States shall submit to Congress and to the Secretary a report on the adequacy of the methodology under section 1874A(f) of the Social Security Act, as added by paragraph (1), and shall include in the report such recommendations as the Comptroller General determines appropriate with respect to the methodology.

(4) REPORT ON USE OF METHODOLOGY IN ASSESSING CONTRACTOR PERFORMANCE.—Not later than October 1, 2003, the Secretary shall submit to Congress a report that describes how the Secretary intends to use such methodology in assessing medicare contractor performance in implementing effective education and outreach programs, including whether to use such methodology as a basis for performance bonuses. The report shall include an analysis of

1 the sources of identified errors and potential changes in
 2 systems of contractors and rules of the Secretary that could
 3 reduce claims error rates.

4 (c) PROVISION OF ACCESS TO AND PROMPT RESPONSES
 5 FROM MEDICARE ADMINISTRATIVE CONTRACTORS.—

6 (1) IN GENERAL.—Section 1874A, as added by section
 7 811(a)(1) and as amended by section 812(a) and sub-
 8 section (b), is further amended by adding at the end the
 9 following new subsection:

10 “(g) COMMUNICATIONS WITH BENEFICIARIES, PROVIDERS
 11 OF SERVICES AND SUPPLIERS.—

12 “(1) COMMUNICATION STRATEGY.—The Secretary
 13 shall develop a strategy for communications with individ-
 14 uals entitled to benefits under part A or enrolled under
 15 part B, or both, and with providers of services and sup-
 16 pliers under this title.

17 “(2) RESPONSE TO WRITTEN INQUIRIES.—Each medi-
 18 care administrative contractor shall, for those providers of
 19 services and suppliers which submit claims to the con-
 20 tractor for claims processing and for those individuals enti-
 21 tled to benefits under part A or enrolled under part B, or
 22 both, with respect to whom claims are submitted for claims
 23 processing, provide general written responses (which may
 24 be through electronic transmission) in a clear, concise, and
 25 accurate manner to inquiries of providers of services, sup-
 26 pliers and individuals entitled to benefits under part A or
 27 enrolled under part B, or both, concerning the programs
 28 under this title within 45 business days of the date of re-
 29 ceipt of such inquiries.

30 “(3) RESPONSE TO TOLL-FREE LINES.—The Secretary
 31 shall ensure that each medicare administrative contractor
 32 shall provide, for those providers of services and suppliers
 33 which submit claims to the contractor for claims processing
 34 and for those individuals entitled to benefits under part A
 35 or enrolled under part B, or both, with respect to whom
 36 claims are submitted for claims processing, a toll-free tele-
 37 phone number at which such individuals, providers of serv-

ices and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate information under this title.

“(4) MONITORING OF CONTRACTOR RESPONSES.—

“(A) IN GENERAL.—Each medicare administrative contractor shall, consistent with standards developed by the Secretary under subparagraph (B)—

“(i) maintain a system for identifying who provides the information referred to in paragraphs (2) and (3); and

“(ii) monitor the accuracy, consistency, and timeliness of the information so provided.

“(B) DEVELOPMENT OF STANDARDS.—

“(i) IN GENERAL.—The Secretary shall establish and make public standards to monitor the accuracy, consistency, and timeliness of the information provided in response to written and telephone inquiries under this subsection. Such standards shall be consistent with the performance requirements established under subsection (b)(3).

“(ii) EVALUATION.—In conducting evaluations of individual medicare administrative contractors, the Secretary shall take into account the results of the monitoring conducted under subparagraph (A) taking into account as performance requirements the standards established under clause (i). The Secretary shall, in consultation with organizations representing providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, establish standards relating to the accuracy, consistency, and timeliness of the information so provided.”.

“(C) DIRECT MONITORING.—Nothing in this paragraph shall be construed as preventing the Secretary from directly monitoring the accuracy, consistency, and timeliness of the information so provided.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect October 1, 2003.

(3) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(g) of the Social Security Act, as added by paragraph (1), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(d) IMPROVED PROVIDER EDUCATION AND TRAINING.—

(1) IN GENERAL.—Section 1889, as added by subsection (a), is amended by adding at the end the following new subsections:

“(b) ENHANCED EDUCATION AND TRAINING.—

“(1) ADDITIONAL RESOURCES.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) \$25,000,000 for each of fiscal years 2004 and 2005 and such sums as may be necessary for succeeding fiscal years.

“(2) USE.—The funds made available under paragraph (1) shall be used to increase the conduct by medicare contractors of education and training of providers of services and suppliers regarding billing, coding, and other appropriate items and may also be used to improve the accuracy, consistency, and timeliness of contractor responses.

“(c) TAILORING EDUCATION AND TRAINING ACTIVITIES FOR SMALL PROVIDERS OR SUPPLIERS.—

“(1) IN GENERAL.—Insofar as a medicare contractor conducts education and training activities, it shall tailor such activities to meet the special needs of small providers of services or suppliers (as defined in paragraph (2)).

“(2) SMALL PROVIDER OF SERVICES OR SUPPLIER.—In this subsection, the term ‘small provider of services or supplier’ means—

1 “(A) a provider of services with fewer than 25 full-
2 time-equivalent employees; or

3 “(B) a supplier with fewer than 10 full-time-equiv-
4 alent employees.”.

5 (2) EFFECTIVE DATE.—The amendment made by
6 paragraph (1) shall take effect on October 1, 2003.

7 (e) REQUIREMENT TO MAINTAIN INTERNET SITES.—

8 (1) IN GENERAL.—Section 1889, as added by sub-
9 section (a) and as amended by subsection (d), is further
10 amended by adding at the end the following new sub-
11 section:

12 “(d) INTERNET SITES; FAQs.—The Secretary, and each
13 medicare contractor insofar as it provides services (including
14 claims processing) for providers of services or suppliers, shall
15 maintain an Internet site which—

16 “(1) provides answers in an easily accessible format to
17 frequently asked questions, and

18 “(2) includes other published materials of the con-
19 tractor,

20 that relate to providers of services and suppliers under the pro-
21 grams under this title (and title XI insofar as it relates to such
22 programs).”.

23 (2) EFFECTIVE DATE.—The amendment made by
24 paragraph (1) shall take effect on October 1, 2003.

25 (f) ADDITIONAL PROVIDER EDUCATION PROVISIONS.—

26 (1) IN GENERAL.—Section 1889, as added by sub-
27 section (a) and as amended by subsections (d) and (e), is
28 further amended by adding at the end the following new
29 subsections:

30 “(e) ENCOURAGEMENT OF PARTICIPATION IN EDUCATION
31 PROGRAM ACTIVITIES.—A medicare contractor may not use a
32 record of attendance at (or failure to attend) educational activi-
33 ties or other information gathered during an educational pro-
34 gram conducted under this section or otherwise by the Sec-
35 retary to select or track providers of services or suppliers for
36 the purpose of conducting any type of audit or prepayment re-
37 view.

“(f) CONSTRUCTION.—Nothing in this section or section 1893(g) shall be construed as providing for disclosure by a medicare contractor of information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits.

“(g) DEFINITIONS.—For purposes of this section, the term ‘medicare contractor’ includes the following:

“(1) A medicare administrative contractor with a contract under section 1874A, including a fiscal intermediary with a contract under section 1816 and a carrier with a contract under section 1842.

“(2) An eligible entity with a contract under section 1893.

Such term does not include, with respect to activities of a specific provider of services or supplier an entity that has no authority under this title or title IX with respect to such activities and such provider of services or supplier.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act.

SEC. 822. SMALL PROVIDER TECHNICAL ASSISTANCE DEMONSTRATION PROGRAM.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary shall establish a demonstration program (in this section referred to as the “demonstration program”) under which technical assistance described in paragraph (2) is made available, upon request and on a voluntary basis, to small providers of services or suppliers in order to improve compliance with the applicable requirements of the programs under medicare program under title XVIII of the Social Security Act (including provisions of title XI of such Act insofar as they relate to such title and are not administered by the Office of the Inspector General of the Department of Health and Human Services).

(2) FORMS OF TECHNICAL ASSISTANCE.—The technical assistance described in this paragraph is—

(A) evaluation and recommendations regarding
 billing and related systems; and

(B) information and assistance regarding policies
 and procedures under the medicare program, including
 coding and reimbursement.

(3) SMALL PROVIDERS OF SERVICES OR SUPPLIERS.—

In this section, the term “small providers of services or
 suppliers” means—

(A) a provider of services with fewer than 25 full-
 time-equivalent employees; or

(B) a supplier with fewer than 10 full-time-equiva-
 lent employees.

(b) QUALIFICATION OF CONTRACTORS.—In conducting the
 demonstration program, the Secretary shall enter into contracts
 with qualified organizations (such as peer review organizations
 or entities described in section 1889(g)(2) of the Social Secu-
 rity Act, as inserted by section 5(f)(1)) with appropriate exper-
 tise with billing systems of the full range of providers of serv-
 ices and suppliers to provide the technical assistance. In award-
 ing such contracts, the Secretary shall consider any prior inves-
 tigations of the entity’s work by the Inspector General of De-
 partment of Health and Human Services or the Comptroller
 General of the United States.

(c) DESCRIPTION OF TECHNICAL ASSISTANCE.—The tech-
 nical assistance provided under the demonstration program
 shall include a direct and in-person examination of billing sys-
 tems and internal controls of small providers of services or sup-
 pliers to determine program compliance and to suggest more
 efficient or effective means of achieving such compliance.

(d) AVOIDANCE OF RECOVERY ACTIONS FOR PROBLEMS
 IDENTIFIED AS CORRECTED.—The Secretary shall provide
 that, absent evidence of fraud and notwithstanding any other
 provision of law, any errors found in a compliance review for
 a small provider of services or supplier that participates in the
 demonstration program shall not be subject to recovery action
 if the technical assistance personnel under the program deter-
 mine that—

(1) the problem that is the subject of the compliance review has been corrected to their satisfaction within 30 days of the date of the visit by such personnel to the small provider of services or supplier; and

(2) such problem remains corrected for such period as is appropriate.

The previous sentence applies only to claims filed as part of the demonstration program and lasts only for the duration of such program and only as long as the small provider of services or supplier is a participant in such program.

(e) GAO EVALUATION.—Not later than 2 years after the date of the date the demonstration program is first implemented, the Comptroller General, in consultation with the Inspector General of the Department of Health and Human Services, shall conduct an evaluation of the demonstration program. The evaluation shall include a determination of whether claims error rates are reduced for small providers of services or suppliers who participated in the program and the extent of improper payments made as a result of the demonstration program. The Comptroller General shall submit a report to the Secretary and the Congress on such evaluation and shall include in such report recommendations regarding the continuation or extension of the demonstration program.

(f) FINANCIAL PARTICIPATION BY PROVIDERS.—The provision of technical assistance to a small provider of services or supplier under the demonstration program is conditioned upon the small provider of services or supplier paying an amount estimated (and disclosed in advance of a provider's or supplier's participation in the program) to be equal to 25 percent of the cost of the technical assistance.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to carry out the demonstration program—

(1) for fiscal year 2004, \$1,000,000, and

(2) for fiscal year 2005, \$6,000,000.

SEC. 823. MEDICARE PROVIDER OMBUDSMAN; MEDICARE BENEFICIARY OMBUDSMAN.

(a) MEDICARE PROVIDER OMBUDSMAN.—Section 1868 (42 U.S.C. 1395ee) is amended—

(1) by adding at the end of the heading the following:

“; MEDICARE PROVIDER OMBUDSMAN”;

(2) by inserting “PRACTICING PHYSICIANS ADVISORY COUNCIL.—(1)” after “(a)”;

(3) in paragraph (1), as so redesignated under paragraph (2), by striking “in this section” and inserting “in this subsection”;

(4) by redesignating subsections (b) and (c) as paragraphs (2) and (3), respectively; and

(5) by adding at the end the following new subsection:

“(b) MEDICARE PROVIDER OMBUDSMAN.—The Secretary shall appoint within the Department of Health and Human Services a Medicare Provider Ombudsman. The Ombudsman shall—

“(1) provide assistance, on a confidential basis, to providers of services and suppliers with respect to complaints, grievances, and requests for information concerning the programs under this title (including provisions of title XI insofar as they relate to this title and are not administered by the Office of the Inspector General of the Department of Health and Human Services) and in the resolution of unclear or conflicting guidance given by the Secretary and medicare contractors to such providers of services and suppliers regarding such programs and provisions and requirements under this title and such provisions; and

“(2) submit recommendations to the Secretary for improvement in the administration of this title and such provisions, including—

“(A) recommendations to respond to recurring patterns of confusion in this title and such provisions (including recommendations regarding suspending imposition of sanctions where there is widespread confusion in program administration), and

1 “(B) recommendations to provide for an appro-
 2 priate and consistent response (including not providing
 3 for audits) in cases of self-identified overpayments by
 4 providers of services and suppliers.

5 The Ombudsman shall not serve as an advocate for any in-
 6 creases in payments or new coverage of services, but may iden-
 7 tify issues and problems in payment or coverage policies.”.

8 (b) MEDICARE BENEFICIARY OMBUDSMAN.—Title XVIII,
 9 as amended by sections 105 and 701, is amended by inserting
 10 after section 1808 the following new section:

11 “MEDICARE BENEFICIARY OMBUDSMAN

12 “SEC. 1809. (a) IN GENERAL.—The Secretary shall ap-
 13 point within the Department of Health and Human Services a
 14 Medicare Beneficiary Ombudsman who shall have expertise and
 15 experience in the fields of health care and education of (and
 16 assistance to) individuals entitled to benefits under this title.

17 “(b) DUTIES.—The Medicare Beneficiary Ombudsman
 18 shall—

19 “(1) receive complaints, grievances, and requests for
 20 information submitted by individuals entitled to benefits
 21 under part A or enrolled under part B, or both, with re-
 22 spect to any aspect of the medicare program;

23 “(2) provide assistance with respect to complaints,
 24 grievances, and requests referred to in paragraph (1),
 25 including—

26 “(A) assistance in collecting relevant information
 27 for such individuals, to seek an appeal of a decision or
 28 determination made by a fiscal intermediary, carrier,
 29 Medicare+Choice organization, or the Secretary; and

30 “(B) assistance to such individuals with any prob-
 31 lems arising from disenrollment from a
 32 Medicare+Choice plan under part C; and

33 “(3) submit annual reports to Congress and the Sec-
 34 retary that describe the activities of the Office and that in-
 35 clude such recommendations for improvement in the admin-
 36 istration of this title as the Ombudsman determines appro-
 37 priate.

1 The Ombudsman shall not serve as an advocate for any in-
 2 creases in payments or new coverage of services, but may iden-
 3 tify issues and problems in payment or coverage policies.

4 “(c) WORKING WITH HEALTH INSURANCE COUNSELING
 5 PROGRAMS.—To the extent possible, the Ombudsman shall
 6 work with health insurance counseling programs (receiving
 7 funding under section 4360 of Omnibus Budget Reconciliation
 8 Act of 1990) to facilitate the provision of information to indi-
 9 viduals entitled to benefits under part A or enrolled under part
 10 B, or both regarding Medicare+Choice plans and changes to
 11 those plans. Nothing in this subsection shall preclude further
 12 collaboration between the Ombudsman and such programs.”.

13 (c) DEADLINE FOR APPOINTMENT.—The Secretary shall
 14 appoint the Medicare Provider Ombudsman and the Medicare
 15 Beneficiary Ombudsman, under the amendments made by sub-
 16 sections (a) and (b), respectively, by not later than 1 year after
 17 the date of the enactment of this Act.

18 (d) FUNDING.—There are authorized to be appropriated to
 19 the Secretary (in appropriate part from the Federal Hospital
 20 Insurance Trust Fund and the Federal Supplementary Medical
 21 Insurance Trust Fund) to carry out the provisions of sub-
 22 section (b) of section 1868 of the Social Security Act (relating
 23 to the Medicare Provider Ombudsman), as added by subsection
 24 (a)(5) and section 1809 of such Act (relating to the Medicare
 25 Beneficiary Ombudsman), as added by subsection (b), such
 26 sums as are necessary for fiscal year 2003 and each succeeding
 27 fiscal year.

28 (e) USE OF CENTRAL, TOLL-FREE NUMBER (1-800-
 29 MEDICARE).—

30 (1) PHONE TRIAGE SYSTEM; LISTING IN MEDICARE
 31 HANDBOOK INSTEAD OF OTHER TOLL-FREE NUMBERS.—
 32 Section 1804(b) (42 U.S.C. 1395b–2(b)) is amended by
 33 adding at the end the following: “The Secretary shall pro-
 34 vide, through the toll-free number 1-800-MEDICARE, for
 35 a means by which individuals seeking information about, or
 36 assistance with, such programs who phone such toll-free
 37 number are transferred (without charge) to appropriate en-

1 titles for the provision of such information or assistance.
 2 Such toll-free number shall be the toll-free number listed
 3 for general information and assistance in the annual notice
 4 under subsection (a) instead of the listing of numbers of
 5 individual contractors.”.

6 (2) MONITORING ACCURACY.—

7 (A) STUDY.—The Comptroller General of the
 8 United States shall conduct a study to monitor the ac-
 9 curacy and consistency of information provided to indi-
 10 viduals entitled to benefits under part A or enrolled
 11 under part B, or both, through the toll-free number 1-
 12 800-MEDICARE, including an assessment of whether
 13 the information provided is sufficient to answer ques-
 14 tions of such individuals. In conducting the study, the
 15 Comptroller General shall examine the education and
 16 training of the individuals providing information
 17 through such number.

18 (B) REPORT.—Not later than 1 year after the
 19 date of the enactment of this Act, the Comptroller Gen-
 20 eral shall submit to Congress a report on the study
 21 conducted under subparagraph (A).

22 **SEC. 824. BENEFICIARY OUTREACH DEMONSTRATION**
 23 **PROGRAM.**

24 (a) IN GENERAL.—The Secretary shall establish a dem-
 25 onstration program (in this section referred to as the “dem-
 26 onstration program”) under which medicare specialists em-
 27 ployed by the Department of Health and Human Services pro-
 28 vide advice and assistance to individuals entitled to benefits
 29 under part A of title XVIII of the Social Security Act, or en-
 30 rolled under part B of such title, or both, regarding the medi-
 31 care program at the location of existing local offices of the So-
 32 cial Security Administration.

33 (b) LOCATIONS.—

34 (1) IN GENERAL.—The demonstration program shall
 35 be conducted in at least 6 offices or areas. Subject to para-
 36 graph (2), in selecting such offices and areas, the Secretary

1 shall provide preference for offices with a high volume of
2 visits by individuals referred to in subsection (a).

3 (2) ASSISTANCE FOR RURAL BENEFICIARIES.—The
4 Secretary shall provide for the selection of at least 2 rural
5 areas to participate in the demonstration program. In con-
6 ducting the demonstration program in such rural areas, the
7 Secretary shall provide for medicare specialists to travel
8 among local offices in a rural area on a scheduled basis.

9 (c) DURATION.—The demonstration program shall be con-
10 ducted over a 3-year period.

11 (d) EVALUATION AND REPORT.—

12 (1) EVALUATION.—The Secretary shall provide for an
13 evaluation of the demonstration program. Such evaluation
14 shall include an analysis of—

15 (A) utilization of, and satisfaction of those individ-
16 uals referred to in subsection (a) with, the assistance
17 provided under the program; and

18 (B) the cost-effectiveness of providing beneficiary
19 assistance through out-stationing medicare specialists
20 at local offices of the Social Security Administration.

21 (2) REPORT.—The Secretary shall submit to Congress
22 a report on such evaluation and shall include in such report
23 recommendations regarding the feasibility of permanently
24 out-stationing medicare specialists at local offices of the So-
25 cial Security Administration.

26 **Subtitle D—Appeals and Recovery**

27 **SEC. 831. TRANSFER OF RESPONSIBILITY FOR MEDI-** 28 **CARE APPEALS.**

29 (a) TRANSITION PLAN.—

30 (1) IN GENERAL.—Not later than October 1, 2003,
31 the Commissioner of Social Security and the Secretary
32 shall develop and transmit to Congress and the Comptroller
33 General of the United States a plan under which the func-
34 tions of administrative law judges responsible for hearing
35 cases under title XVIII of the Social Security Act (and re-
36 lated provisions in title XI of such Act) are transferred
37 from the responsibility of the Commissioner and the Social

1 Security Administration to the Secretary and the Depart-
2 ment of Health and Human Services.

3 (2) GAO EVALUATION.—The Comptroller General of
4 the United States shall evaluate the plan and, not later
5 than the date that is 6 months after the date on which the
6 plan is received by the Comptroller General, shall submit
7 to Congress a report on such evaluation.

8 (b) TRANSFER OF ADJUDICATION AUTHORITY.—

9 (1) IN GENERAL.—Not earlier than July 1, 2004, and
10 not later than October 1, 2004, the Commissioner of Social
11 Security and the Secretary shall implement the transition
12 plan under subsection (a) and transfer the administrative
13 law judge functions described in such subsection from the
14 Social Security Administration to the Secretary.

15 (2) ASSURING INDEPENDENCE OF JUDGES.—The Sec-
16 retary shall assure the independence of administrative law
17 judges performing the administrative law judge functions
18 transferred under paragraph (1) from the Centers for
19 Medicare & Medicaid Services and its contractors.

20 (3) GEOGRAPHIC DISTRIBUTION.—The Secretary shall
21 provide for an appropriate geographic distribution of ad-
22 ministrative law judges performing the administrative law
23 judge functions transferred under paragraph (1) through-
24 out the United States to ensure timely access to such
25 judges.

26 (4) HIRING AUTHORITY.—Subject to the amounts pro-
27 vided in advance in appropriations Act, the Secretary shall
28 have authority to hire administrative law judges to hear
29 such cases, giving priority to those judges with prior experi-
30 ence in handling medicare appeals and in a manner con-
31 sistent with paragraph (3), and to hire support staff for
32 such judges.

33 (5) FINANCING.—Amounts payable under law to the
34 Commissioner for administrative law judges performing the
35 administrative law judge functions transferred under para-
36 graph (1) from the Federal Hospital Insurance Trust Fund
37 and the Federal Supplementary Medical Insurance Trust

Fund shall become payable to the Secretary for the functions so transferred.

(6) **SHARED RESOURCES.**—The Secretary shall enter into such arrangements with the Commissioner as may be appropriate with respect to transferred functions of administrative law judges to share office space, support staff, and other resources, with appropriate reimbursement from the Trust Funds described in paragraph (5).

(c) **INCREASED FINANCIAL SUPPORT.**—In addition to any amounts otherwise appropriated, to ensure timely action on appeals before administrative law judges and the Departmental Appeals Board consistent with section 1869 of the Social Security Act (as amended by section 521 of BIPA, 114 Stat. 2763A–534), there are authorized to be appropriated (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to the Secretary such sums as are necessary for fiscal year 2004 and each subsequent fiscal year to—

(1) increase the number of administrative law judges (and their staffs) under subsection (b)(4);

(2) improve education and training opportunities for administrative law judges (and their staffs); and

(3) increase the staff of the Departmental Appeals Board.

(d) **CONFORMING AMENDMENT.**—Section 1869(f)(2)(A)(i) (42 U.S.C. 1395ff(f)(2)(A)(i)), as added by section 522(a) of BIPA (114 Stat. 2763A–543), is amended by striking “of the Social Security Administration”.

SEC. 832. PROCESS FOR EXPEDITED ACCESS TO REVIEW.

(a) **EXPEDITED ACCESS TO JUDICIAL REVIEW.**—Section 1869(b) (42 U.S.C. 1395ff(b)) as amended by BIPA, is amended—

(1) in paragraph (1)(A), by inserting “, subject to paragraph (2),” before “to judicial review of the Secretary’s final decision”;

(2) in paragraph (1)(F)—

(A) by striking clause (ii);

(B) by striking “PROCEEDING” and all that follows through “DETERMINATION” and inserting “DETERMINATIONS AND RECONSIDERATIONS”; and

(C) by redesignating subclauses (I) and (II) as clauses (i) and (ii) and by moving the indentation of such subclauses (and the matter that follows) 2 ems to the left; and

(3) by adding at the end the following new paragraph:

“(2) EXPEDITED ACCESS TO JUDICIAL REVIEW.—

“(A) IN GENERAL.—The Secretary shall establish a process under which a provider of services or supplier that furnishes an item or service or an individual entitled to benefits under part A or enrolled under part B, or both, who has filed an appeal under paragraph (1) may obtain access to judicial review when a review panel (described in subparagraph (D)), on its own motion or at the request of the appellant, determines that no entity in the administrative appeals process has the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute. The appellant may make such request only once with respect to a question of law or regulation in a case of an appeal.

“(B) PROMPT DETERMINATIONS.—If, after or coincident with appropriately filing a request for an administrative hearing, the appellant requests a determination by the appropriate review panel that no review panel has the authority to decide the question of law or regulations relevant to the matters in controversy and that there is no material issue of fact in dispute and if such request is accompanied by the documents and materials as the appropriate review panel shall require for purposes of making such determination, such review panel shall make a determination on the request in writing within 60 days after the date such review panel receives the request and such accompanying documents and materials. Such a determina-

tion by such review panel shall be considered a final decision and not subject to review by the Secretary.

“(C) ACCESS TO JUDICIAL REVIEW.—

“(i) IN GENERAL.—If the appropriate review panel—

“(I) determines that there are no material issues of fact in dispute and that the only issue is one of law or regulation that no review panel has the authority to decide; or

“(II) fails to make such determination within the period provided under subparagraph (B);

then the appellant may bring a civil action as described in this subparagraph.

“(ii) DEADLINE FOR FILING.—Such action shall be filed, in the case described in—

“(I) clause (i)(I), within 60 days of date of the determination described in such subparagraph; or

“(II) clause (i)(II), within 60 days of the end of the period provided under subparagraph (B) for the determination.

“(iii) VENUE.—Such action shall be brought in the district court of the United States for the judicial district in which the appellant is located (or, in the case of an action brought jointly by more than one applicant, the judicial district in which the greatest number of applicants are located) or in the district court for the District of Columbia.

“(iv) INTEREST ON AMOUNTS IN CONTROVERSY.—Where a provider of services or supplier seeks judicial review pursuant to this paragraph, the amount in controversy shall be subject to annual interest beginning on the first day of the first month beginning after the 60-day period as determined pursuant to clause (ii) and equal to the rate of interest on obligations issued for purchase

by the Federal Hospital Insurance Trust Fund and by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this paragraph is commenced, to be awarded by the reviewing court in favor of the prevailing party. No interest awarded pursuant to the preceding sentence shall be deemed income or cost for the purposes of determining reimbursement due providers of services or suppliers under this Act.

“(D) REVIEW PANELS.—For purposes of this subsection, a ‘review panel’ is a panel consisting of 3 members (who shall be administrative law judges, members of the Departmental Appeals Board, or qualified individuals associated with a qualified independent contractor (as defined in subsection (c)(2)) or with another independent entity) designated by the Secretary for purposes of making determinations under this paragraph.”.

(b) APPLICATION TO PROVIDER AGREEMENT DETERMINATIONS.—Section 1866(h)(1) (42 U.S.C. 1395cc(h)(1)) is amended—

(1) by inserting “(A)” after “(h)(1)”; and

(2) by adding at the end the following new subparagraph:

“(B) An institution or agency described in subparagraph (A) that has filed for a hearing under subparagraph (A) shall have expedited access to judicial review under this subparagraph in the same manner as providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, may obtain expedited access to judicial review under the process established under section 1869(b)(2). Nothing in this subparagraph shall be construed to affect the application of any remedy imposed under section 1819 during the pendency of an appeal under this subparagraph.”.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to appeals filed on or after October 1, 2003.

(d) EXPEDITED REVIEW OF CERTAIN PROVIDER AGREEMENT DETERMINATIONS.—

(1) TERMINATION AND CERTAIN OTHER IMMEDIATE REMEDIES.—The Secretary shall develop and implement a process to expedite proceedings under sections 1866(h) of the Social Security Act (42 U.S.C. 1395cc(h)) in which the remedy of termination of participation, or a remedy described in clause (i) or (iii) of section 1819(h)(2)(B) of such Act (42 U.S.C. 1395i–3(h)(2)(B)) which is applied on an immediate basis, has been imposed. Under such process priority shall be provided in cases of termination.

(2) INCREASED FINANCIAL SUPPORT.—In addition to any amounts otherwise appropriated, to reduce by 50 percent the average time for administrative determinations on appeals under section 1866(h) of the Social Security Act (42 U.S.C. 1395cc(h)), there are authorized to be appropriated (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to the Secretary such additional sums for fiscal year 2004 and each subsequent fiscal year as may be necessary. The purposes for which such amounts are available include increasing the number of administrative law judges (and their staffs) and the appellate level staff at the Departmental Appeals Board of the Department of Health and Human Services and educating such judges and staffs on long-term care issues.

SEC. 833. REVISIONS TO MEDICARE APPEALS PROCESS.

(a) REQUIRING FULL AND EARLY PRESENTATION OF EVIDENCE.—

(1) IN GENERAL.—Section 1869(b) (42 U.S.C. 1395ff(b)), as amended by BIPA and as amended by section 832(a), is further amended by adding at the end the following new paragraph:

“(3) REQUIRING FULL AND EARLY PRESENTATION OF EVIDENCE BY PROVIDERS.—A provider of services or supplier may not introduce evidence in any appeal under this section that was not presented at the reconsideration con-

ducted by the qualified independent contractor under subsection (c), unless there is good cause which precluded the introduction of such evidence at or before that reconsideration.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on October 1, 2003.

(b) USE OF PATIENTS’ MEDICAL RECORDS.—Section 1869(c)(3)(B)(i) (42 U.S.C. 1395ff(c)(3)(B)(i)), as amended by BIPA, is amended by inserting “(including the medical records of the individual involved)” after “clinical experience”.

(c) NOTICE REQUIREMENTS FOR MEDICARE APPEALS.—

(1) INITIAL DETERMINATIONS AND REDETERMINATIONS.—Section 1869(a) (42 U.S.C. 1395ff(a)), as amended by BIPA, is amended by adding at the end the following new paragraph:

“(4) REQUIREMENTS OF NOTICE OF DETERMINATIONS AND REDETERMINATIONS.—A written notice of a determination on an initial determination or on a redetermination, insofar as such determination or redetermination results in a denial of a claim for benefits, shall include—

“(A) the specific reasons for the determination, including—

“(i) upon request, the provision of the policy, manual, or regulation used in making the determination; and

“(ii) as appropriate in the case of a redetermination, a summary of the clinical or scientific evidence used in making the determination;

“(B) the procedures for obtaining additional information concerning the determination or redetermination; and

“(C) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination or appeal under this section.

The written notice on a redetermination shall be provided in printed form and written in a manner calculated to be

understood by the individual entitled to benefits under part A or enrolled under part B, or both.”.

(2) RECONSIDERATIONS.—Section 1869(c)(3)(E) (42 U.S.C. 1395ff(c)(3)(E)), as amended by BIPA, is amended—

(A) by inserting “be written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include (to the extent appropriate)” after “in writing, ”; and

(B) by inserting “and a notification of the right to appeal such determination and instructions on how to initiate such appeal under this section” after “such decision, ”.

(3) APPEALS.—Section 1869(d) (42 U.S.C. 1395ff(d)), as amended by BIPA, is amended—

(A) in the heading, by inserting “; NOTICE” after “SECRETARY”; and

(B) by adding at the end the following new paragraph:

“(4) NOTICE.—Notice of the decision of an administrative law judge shall be in writing in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include—

“(A) the specific reasons for the determination (including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination);

“(B) the procedures for obtaining additional information concerning the decision; and

“(C) notification of the right to appeal the decision and instructions on how to initiate such an appeal under this section.”.

(4) SUBMISSION OF RECORD FOR APPEAL.—Section 1869(c)(3)(J)(i) (42 U.S.C. 1395ff(c)(3)(J)(i)) by striking “prepare” and inserting “submit” and by striking “with re-

spect to” and all that follows through “and relevant policies”.

(d) QUALIFIED INDEPENDENT CONTRACTORS.—

(1) ELIGIBILITY REQUIREMENTS OF QUALIFIED INDEPENDENT CONTRACTORS.—Section 1869(c)(3) (42 U.S.C. 1395ff(c)(3)), as amended by BIPA, is amended—

(A) in subparagraph (A), by striking “sufficient training and expertise in medical science and legal matters” and inserting “sufficient medical, legal, and other expertise (including knowledge of the program under this title) and sufficient staffing”; and

(B) by adding at the end the following new subparagraph:

“(K) INDEPENDENCE REQUIREMENTS.—

“(i) IN GENERAL.—Subject to clause (ii), a qualified independent contractor shall not conduct any activities in a case unless the entity—

“(I) is not a related party (as defined in subsection (g)(5));

“(II) does not have a material familial, financial, or professional relationship with such a party in relation to such case; and

“(III) does not otherwise have a conflict of interest with such a party.

“(ii) EXCEPTION FOR REASONABLE COMPENSATION.—Nothing in clause (i) shall be construed to prohibit receipt by a qualified independent contractor of compensation from the Secretary for the conduct of activities under this section if the compensation is provided consistent with clause (iii).

“(iii) LIMITATIONS ON ENTITY COMPENSATION.—Compensation provided by the Secretary to a qualified independent contractor in connection with reviews under this section shall not be contingent on any decision rendered by the contractor or by any reviewing professional.”.

(2) ELIGIBILITY REQUIREMENTS FOR REVIEWERS.—
 Section 1869 (42 U.S.C. 1395ff), as amended by BIPA, is
 amended—

(A) by amending subsection (c)(3)(D) to read as
 follows:

“(D) QUALIFICATIONS FOR REVIEWERS.—The re-
 quirements of subsection (g) shall be met (relating to
 qualifications of reviewing professionals).”; and

(B) by adding at the end the following new sub-
 section:

“(g) QUALIFICATIONS OF REVIEWERS.—

“(1) IN GENERAL.—In reviewing determinations under
 this section, a qualified independent contractor shall assure
 that—

“(A) each individual conducting a review shall
 meet the qualifications of paragraph (2);

“(B) compensation provided by the contractor to
 each such reviewer is consistent with paragraph (3);
 and

“(C) in the case of a review by a panel described
 in subsection (c)(3)(B) composed of physicians or other
 health care professionals (each in this subsection re-
 ferred to as a ‘reviewing professional’), each reviewing
 professional meets the qualifications described in para-
 graph (4) and, where a claim is regarding the fur-
 nishing of treatment by a physician (allopathic or os-
 teopathic) or the provision of items or services by a
 physician (allopathic or osteopathic), each reviewing
 professional shall be a physician (allopathic or osteo-
 pathic).

“(2) INDEPENDENCE.—

“(A) IN GENERAL.—Subject to subparagraph (B),
 each individual conducting a review in a case shall—

“(i) not be a related party (as defined in para-
 graph (5));

“(ii) not have a material familial, financial, or professional relationship with such a party in the case under review; and

“(iii) not otherwise have a conflict of interest with such a party.

“(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to—

“(i) prohibit an individual, solely on the basis of a participation agreement with a fiscal intermediary, carrier, or other contractor, from serving as a reviewing professional if—

“(I) the individual is not involved in the provision of items or services in the case under review;

“(II) the fact of such an agreement is disclosed to the Secretary and the individual entitled to benefits under part A or enrolled under part B, or both, (or authorized representative) and neither party objects; and

“(III) the individual is not an employee of the intermediary, carrier, or contractor and does not provide services exclusively or primarily to or on behalf of such intermediary, carrier, or contractor;

“(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as a reviewer merely on the basis of having such staff privileges if the existence of such privileges is disclosed to the Secretary and such individual (or authorized representative), and neither party objects; or

“(iii) prohibit receipt of compensation by a reviewing professional from a contractor if the compensation is provided consistent with paragraph (3).

For purposes of this paragraph, the term ‘participation agreement’ means an agreement relating to the provi-

1 sion of health care services by the individual and does
 2 not include the provision of services as a reviewer
 3 under this subsection.

4 “(3) LIMITATIONS ON REVIEWER COMPENSATION.—
 5 Compensation provided by a qualified independent con-
 6 tractor to a reviewer in connection with a review under this
 7 section shall not be contingent on the decision rendered by
 8 the reviewer.

9 “(4) LICENSURE AND EXPERTISE.—Each reviewing
 10 professional shall be—

11 “(A) a physician (allopathic or osteopathic) who is
 12 appropriately credentialed or licensed in one or more
 13 States to deliver health care services and has medical
 14 expertise in the field of practice that is appropriate for
 15 the items or services at issue; or

16 “(B) a health care professional who is legally au-
 17 thorized in one or more States (in accordance with
 18 State law or the State regulatory mechanism provided
 19 by State law) to furnish the health care items or serv-
 20 ices at issue and has medical expertise in the field of
 21 practice that is appropriate for such items or services.

22 “(5) RELATED PARTY DEFINED.—For purposes of this
 23 section, the term ‘related party’ means, with respect to a
 24 case under this title involving a specific individual entitled
 25 to benefits under part A or enrolled under part B, or both,
 26 any of the following:

27 “(A) The Secretary, the medicare administrative
 28 contractor involved, or any fiduciary, officer, director,
 29 or employee of the Department of Health and Human
 30 Services, or of such contractor.

31 “(B) The individual (or authorized representative).

32 “(C) The health care professional that provides
 33 the items or services involved in the case.

34 “(D) The institution at which the items or services
 35 (or treatment) involved in the case are provided.

“(E) The manufacturer of any drug or other item that is included in the items or services involved in the case.

“(F) Any other party determined under any regulations to have a substantial interest in the case involved.”.

(3) EFFECTIVE DATE.—The amendments made by paragraphs (1) and (2) shall be effective as if included in the enactment of the respective provisions of subtitle C of title V of BIPA, (114 Stat. 2763A–534).

(4) TRANSITION.—In applying section 1869(g) of the Social Security Act (as added by paragraph (2)), any reference to a medicare administrative contractor shall be deemed to include a reference to a fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and a carrier under section 1842 of such Act (42 U.S.C. 1395u).

SEC. 834. PREPAYMENT REVIEW.

(a) IN GENERAL.—Section 1874A, as added by section 811(a)(1) and as amended by sections 812(b), 821(b)(1), and 831(c)(1), is further amended by adding at the end the following new subsection:

“(h) CONDUCT OF PREPAYMENT REVIEW.—

“(1) CONDUCT OF RANDOM PREPAYMENT REVIEW.—

“(A) IN GENERAL.—A medicare administrative contractor may conduct random prepayment review only to develop a contractor-wide or program-wide claims payment error rates or under such additional circumstances as may be provided under regulations, developed in consultation with providers of services and suppliers.

“(B) USE OF STANDARD PROTOCOLS WHEN CONDUCTING PREPAYMENT REVIEWS.—When a medicare administrative contractor conducts a random prepayment review, the contractor may conduct such review only in accordance with a standard protocol for random prepayment audits developed by the Secretary.

“(C) CONSTRUCTION.—Nothing in this paragraph shall be construed as preventing the denial of payments for claims actually reviewed under a random prepayment review.

“(D) RANDOM PREPAYMENT REVIEW.—For purposes of this subsection, the term ‘random prepayment review’ means a demand for the production of records or documentation absent cause with respect to a claim.

“(2) LIMITATIONS ON NON-RANDOM PREPAYMENT REVIEW.—

“(A) LIMITATIONS ON INITIATION OF NON-RANDOM PREPAYMENT REVIEW.—A medicare administrative contractor may not initiate non-random prepayment review of a provider of services or supplier based on the initial identification by that provider of services or supplier of an improper billing practice unless there is a likelihood of sustained or high level of payment error (as defined in subsection (i)(3)(A)).

“(B) TERMINATION OF NON-RANDOM PREPAYMENT REVIEW.—The Secretary shall issue regulations relating to the termination, including termination dates, of non-random prepayment review. Such regulations may vary such a termination date based upon the differences in the circumstances triggering prepayment review.”.

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in this subsection, the amendment made by subsection (a) shall take effect 1 year after the date of the enactment of this Act.

(2) DEADLINE FOR PROMULGATION OF CERTAIN REGULATIONS.—The Secretary shall first issue regulations under section 1874A(h) of the Social Security Act, as added by subsection (a), by not later than 1 year after the date of the enactment of this Act.

(3) APPLICATION OF STANDARD PROTOCOLS FOR RANDOM PREPAYMENT REVIEW.—Section 1874A(h)(1)(B) of the Social Security Act, as added by subsection (a), shall

1 apply to random prepayment reviews conducted on or after
 2 such date (not later than 1 year after the date of the enact-
 3 ment of this Act) as the Secretary shall specify.

4 (c) APPLICATION TO FISCAL INTERMEDIARIES AND CAR-
 5 RIERS.—The provisions of section 1874A(h) of the Social Secu-
 6 rity Act, as added by subsection (a), shall apply to each fiscal
 7 intermediary under section 1816 of the Social Security Act (42
 8 U.S.C. 1395h) and each carrier under section 1842 of such Act
 9 (42 U.S.C. 1395u) in the same manner as they apply to medi-
 10 care administrative contractors under such provisions.

11 **SEC. 835. RECOVERY OF OVERPAYMENTS.**

12 (a) IN GENERAL.—Section 1893 (42 U.S.C. 1395ddd) is
 13 amended by adding at the end the following new subsection:

14 “(f) RECOVERY OF OVERPAYMENTS.—

15 “(1) USE OF REPAYMENT PLANS.—

16 “(A) IN GENERAL.—If the repayment, within 30
 17 days by a provider of services or supplier, of an over-
 18 payment under this title would constitute a hardship
 19 (as defined in subparagraph (B)), subject to subpara-
 20 graph (C), upon request of the provider of services or
 21 supplier the Secretary shall enter into a plan with the
 22 provider of services or supplier for the repayment
 23 (through offset or otherwise) of such overpayment over
 24 a period of at least 6 months but not longer than 3
 25 years (or not longer than 5 years in the case of extreme
 26 hardship, as determined by the Secretary). Interest
 27 shall accrue on the balance through the period of re-
 28 payment. Such plan shall meet terms and conditions
 29 determined to be appropriate by the Secretary.

30 “(B) HARDSHIP.—

31 “(i) IN GENERAL.—For purposes of subpara-
 32 graph (A), the repayment of an overpayment (or
 33 overpayments) within 30 days is deemed to con-
 34 stitute a hardship if—

35 “(I) in the case of a provider of services
 36 that files cost reports, the aggregate amount of
 37 the overpayments exceeds 10 percent of the

1 amount paid under this title to the provider of
 2 services for the cost reporting period covered by
 3 the most recently submitted cost report; or

4 “(II) in the case of another provider of
 5 services or supplier, the aggregate amount of
 6 the overpayments exceeds 10 percent of the
 7 amount paid under this title to the provider of
 8 services or supplier for the previous calendar
 9 year.

10 “(ii) RULE OF APPLICATION.—The Secretary
 11 shall establish rules for the application of this sub-
 12 paragraph in the case of a provider of services or
 13 supplier that was not paid under this title during
 14 the previous year or was paid under this title only
 15 during a portion of that year.

16 “(iii) TREATMENT OF PREVIOUS OVERPAY-
 17 MENTS.—If a provider of services or supplier has
 18 entered into a repayment plan under subparagraph
 19 (A) with respect to a specific overpayment amount,
 20 such payment amount under the repayment plan
 21 shall not be taken into account under clause (i)
 22 with respect to subsequent overpayment amounts.

23 “(C) EXCEPTIONS.—Subparagraph (A) shall not
 24 apply if—

25 “(i) the Secretary has reason to suspect that
 26 the provider of services or supplier may file for
 27 bankruptcy or otherwise cease to do business or
 28 discontinue participation in the program under this
 29 title; or

30 “(ii) there is an indication of fraud or abuse
 31 committed against the program.

32 “(D) IMMEDIATE COLLECTION IF VIOLATION OF
 33 REPAYMENT PLAN.—If a provider of services or sup-
 34 plier fails to make a payment in accordance with a re-
 35 payment plan under this paragraph, the Secretary may
 36 immediately seek to offset or otherwise recover the

total balance outstanding (including applicable interest) under the repayment plan.

“(E) RELATION TO NO FAULT PROVISION.—Nothing in this paragraph shall be construed as affecting the application of section 1870(c) (relating to no adjustment in the cases of certain overpayments).

“(2) LIMITATION ON RECOUPMENT.—

“(A) IN GENERAL.—In the case of a provider of services or supplier that is determined to have received an overpayment under this title and that seeks a reconsideration by a qualified independent contractor on such determination under section 1869(b)(1), the Secretary may not take any action (or authorize any other person, including any medicare contractor, as defined in subparagraph (C) to recoup the overpayment until the date the decision on the reconsideration has been rendered. If the provisions of section 1869(b)(1) (providing for such a reconsideration by a qualified independent contractor) are not in effect, in applying the previous sentence any reference to such a reconsideration shall be treated as a reference to a redetermination by the fiscal intermediary or carrier involved.

“(B) COLLECTION WITH INTEREST.—Insofar as the determination on such appeal is against the provider of services or supplier, interest on the overpayment shall accrue on and after the date of the original notice of overpayment. Insofar as such determination against the provider of services or supplier is later reversed, the Secretary shall provide for repayment of the amount recouped plus interest at the same rate as would apply under the previous sentence for the period in which the amount was recouped.

“(C) MEDICARE CONTRACTOR DEFINED.—For purposes of this subsection, the term ‘medicare contractor’ has the meaning given such term in section 1889(g).

“(3) LIMITATION ON USE OF EXTRAPOLATION.—A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless—

“(A) there is a sustained or high level of payment error (as defined by the Secretary by regulation); or

“(B) documented educational intervention has failed to correct the payment error (as determined by the Secretary).

“(4) PROVISION OF SUPPORTING DOCUMENTATION.—In the case of a provider of services or supplier with respect to which amounts were previously overpaid, a medicare contractor may request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing.

“(5) CONSENT SETTLEMENT REFORMS.—

“(A) IN GENERAL.—The Secretary may use a consent settlement (as defined in subparagraph (D)) to settle a projected overpayment.

“(B) OPPORTUNITY TO SUBMIT ADDITIONAL INFORMATION BEFORE CONSENT SETTLEMENT OFFER.—Before offering a provider of services or supplier a consent settlement, the Secretary shall—

“(i) communicate to the provider of services or supplier—

“(I) that, based on a review of the medical records requested by the Secretary, a preliminary evaluation of those records indicates that there would be an overpayment;

“(II) the nature of the problems identified in such evaluation; and

“(III) the steps that the provider of services or supplier should take to address the problems; and

“(ii) provide for a 45-day period during which the provider of services or supplier may furnish ad-

ditional information concerning the medical records for the claims that had been reviewed.

“(C) CONSENT SETTLEMENT OFFER.—The Secretary shall review any additional information furnished by the provider of services or supplier under subparagraph (B)(ii). Taking into consideration such information, the Secretary shall determine if there still appears to be an overpayment. If so, the Secretary—

“(i) shall provide notice of such determination to the provider of services or supplier, including an explanation of the reason for such determination; and

“(ii) in order to resolve the overpayment, may offer the provider of services or supplier—

“(I) the opportunity for a statistically valid random sample; or

“(II) a consent settlement.

The opportunity provided under clause (ii)(I) does not waive any appeal rights with respect to the alleged overpayment involved.

“(D) CONSENT SETTLEMENT DEFINED.—For purposes of this paragraph, the term ‘consent settlement’ means an agreement between the Secretary and a provider of services or supplier whereby both parties agree to settle a projected overpayment based on less than a statistically valid sample of claims and the provider of services or supplier agrees not to appeal the claims involved.

“(6) NOTICE OF OVER-UTILIZATION OF CODES.—The Secretary shall establish, in consultation with organizations representing the classes of providers of services and suppliers, a process under which the Secretary provides for notice to classes of providers of services and suppliers served by the contractor in cases in which the contractor has identified that particular billing codes may be overutilized by that class of providers of services or suppliers under the

1 programs under this title (or provisions of title XI insofar
2 as they relate to such programs).

3 “(7) PAYMENT AUDITS.—

4 “(A) WRITTEN NOTICE FOR POST-PAYMENT AU-
5 DITS.—Subject to subparagraph (C), if a medicare con-
6 tractor decides to conduct a post-payment audit of a
7 provider of services or supplier under this title, the con-
8 tractor shall provide the provider of services or supplier
9 with written notice (which may be in electronic form)
10 of the intent to conduct such an audit.

11 “(B) EXPLANATION OF FINDINGS FOR ALL AU-
12 DITS.—Subject to subparagraph (C), if a medicare con-
13 tractor audits a provider of services or supplier under
14 this title, the contractor shall—

15 “(i) give the provider of services or supplier a
16 full review and explanation of the findings of the
17 audit in a manner that is understandable to the
18 provider of services or supplier and permits the de-
19 velopment of an appropriate corrective action plan;

20 “(ii) inform the provider of services or supplier
21 of the appeal rights under this title as well as con-
22 sent settlement options (which are at the discretion
23 of the Secretary);

24 “(iii) give the provider of services or supplier
25 an opportunity to provide additional information to
26 the contractor; and

27 “(iv) take into account information provided,
28 on a timely basis, by the provider of services or
29 supplier under clause (iii).

30 “(C) EXCEPTION.—Subparagraphs (A) and (B)
31 shall not apply if the provision of notice or findings
32 would compromise pending law enforcement activities,
33 whether civil or criminal, or reveal findings of law en-
34 forcement-related audits.

35 “(8) STANDARD METHODOLOGY FOR PROBE SAM-
36 PLING.—The Secretary shall establish a standard method-
37 ology for medicare contractors to use in selecting a sample

1 of claims for review in the case of an abnormal billing pat-
 2 tern.”.

3 (b) EFFECTIVE DATES AND DEADLINES.—

4 (1) USE OF REPAYMENT PLANS.—Section 1893(f)(1)
 5 of the Social Security Act, as added by subsection (a), shall
 6 apply to requests for repayment plans made after the date
 7 of the enactment of this Act.

8 (2) LIMITATION ON RECOUPMENT.—Section
 9 1893(f)(2) of the Social Security Act, as added by sub-
 10 section (a), shall apply to actions taken after the date of
 11 the enactment of this Act.

12 (3) USE OF EXTRAPOLATION.—Section 1893(f)(3) of
 13 the Social Security Act, as added by subsection (a), shall
 14 apply to statistically valid random samples initiated after
 15 the date that is 1 year after the date of the enactment of
 16 this Act.

17 (4) PROVISION OF SUPPORTING DOCUMENTATION.—
 18 Section 1893(f)(4) of the Social Security Act, as added by
 19 subsection (a), shall take effect on the date of the enact-
 20 ment of this Act.

21 (5) CONSENT SETTLEMENT.—Section 1893(f)(5) of
 22 the Social Security Act, as added by subsection (a), shall
 23 apply to consent settlements entered into after the date of
 24 the enactment of this Act.

25 (6) NOTICE OF OVERUTILIZATION.—Not later than 1
 26 year after the date of the enactment of this Act, the Sec-
 27 retary shall first establish the process for notice of over-
 28 utilization of billing codes under section 1893A(f)(6) of the
 29 Social Security Act, as added by subsection (a).

30 (7) PAYMENT AUDITS.—Section 1893A(f)(7) of the
 31 Social Security Act, as added by subsection (a), shall apply
 32 to audits initiated after the date of the enactment of this
 33 Act.

34 (8) STANDARD FOR ABNORMAL BILLING PATTERNS.—
 35 Not later than 1 year after the date of the enactment of
 36 this Act, the Secretary shall first establish a standard
 37 methodology for selection of sample claims for abnormal

1 billing patterns under section 1893(f)(8) of the Social Se-
 2 curity Act, as added by subsection (a).

3 **SEC. 836. PROVIDER ENROLLMENT PROCESS; RIGHT OF**
 4 **APPEAL.**

5 (a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is
 6 amended—

7 (1) by adding at the end of the heading the following:

8 “; ENROLLMENT PROCESSES”; and

9 (2) by adding at the end the following new subsection:

10 “(j) ENROLLMENT PROCESS FOR PROVIDERS OF SERV-
 11 ICES AND SUPPLIERS.—

12 “(1) ENROLLMENT PROCESS.—

13 “(A) IN GENERAL.—The Secretary shall establish
 14 by regulation a process for the enrollment of providers
 15 of services and suppliers under this title.

16 “(B) DEADLINES.—The Secretary shall establish
 17 by regulation procedures under which there are dead-
 18 lines for actions on applications for enrollment (and, if
 19 applicable, renewal of enrollment). The Secretary shall
 20 monitor the performance of medicare administrative
 21 contractors in meeting the deadlines established under
 22 this subparagraph.

23 “(C) CONSULTATION BEFORE CHANGING PRO-
 24 VIDER ENROLLMENT FORMS.—The Secretary shall con-
 25 sult with providers of services and suppliers before
 26 making changes in the provider enrollment forms re-
 27 quired of such providers and suppliers to be eligible to
 28 submit claims for which payment may be made under
 29 this title.

30 “(2) HEARING RIGHTS IN CASES OF DENIAL OR NON-
 31 RENEWAL.—A provider of services or supplier whose appli-
 32 cation to enroll (or, if applicable, to renew enrollment)
 33 under this title is denied may have a hearing and judicial
 34 review of such denial under the procedures that apply
 35 under subsection (h)(1)(A) to a provider of services that is
 36 dissatisfied with a determination by the Secretary.”.

37 (b) EFFECTIVE DATES.—

(1) ENROLLMENT PROCESS.—The Secretary shall provide for the establishment of the enrollment process under section 1866(j)(1) of the Social Security Act, as added by subsection (a)(2), within 6 months after the date of the enactment of this Act.

(2) CONSULTATION.—Section 1866(j)(1)(C) of the Social Security Act, as added by subsection (a)(2), shall apply with respect to changes in provider enrollment forms made on or after January 1, 2003.

(3) HEARING RIGHTS.—Section 1866(j)(2) of the Social Security Act, as added by subsection (a)(2), shall apply to denials occurring on or after such date (not later than 1 year after the date of the enactment of this Act) as the Secretary specifies.

SEC. 837. PROCESS FOR CORRECTION OF MINOR ERRORS AND OMISSIONS ON CLAIMS WITHOUT PURSUING APPEALS PROCESS.

The Secretary shall develop, in consultation with appropriate medicare contractors (as defined in section 1889(g) of the Social Security Act, as inserted by section 821(a)(1)) and representatives of providers of services and suppliers, a process whereby, in the case of minor errors or omissions (as defined by the Secretary) that are detected in the submission of claims under the programs under title XVIII of such Act, a provider of services or supplier is given an opportunity to correct such an error or omission without the need to initiate an appeal. Such process shall include the ability to resubmit corrected claims.

SEC. 838. PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES; ADVANCE BENEFICIARY NOTICES.

(a) IN GENERAL.—Section 1869 (42 U.S.C. 1395ff(b)), as amended by sections 521 and 522 of BIPA and section 833(d)(2)(B), is further amended by adding at the end the following new subsection:

“(h) PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES.—

“(1) ESTABLISHMENT OF PROCESS.—

1 “(A) IN GENERAL.—With respect to a medicare
 2 administrative contractor that has a contract under
 3 section 1874A that provides for making payments
 4 under this title with respect to eligible items and serv-
 5 ices described in subparagraph (C), the Secretary shall
 6 establish a prior determination process that meets the
 7 requirements of this subsection and that shall be ap-
 8 plied by such contractor in the case of eligible request-
 9 ers.

10 “(B) ELIGIBLE REQUESTER.—For purposes of
 11 this subsection, each of the following shall be an eligi-
 12 ble requester:

13 “(i) A physician, but only with respect to eligi-
 14 ble items and services for which the physician may
 15 be paid directly.

16 “(ii) An individual entitled to benefits under
 17 this title, but only with respect to an item or serv-
 18 ice for which the individual receives, from the phy-
 19 sician who may be paid directly for the item or
 20 service, an advance beneficiary notice under section
 21 1879(a) that payment may not be made (or may no
 22 longer be made) for the item or service under this
 23 title.

24 “(C) ELIGIBLE ITEMS AND SERVICES.—For pur-
 25 poses of this subsection and subject to paragraph (2),
 26 eligible items and services are items and services which
 27 are physicians’ services (as defined in paragraph (4)(A)
 28 of section 1848(f) for purposes of calculating the sus-
 29 tainable growth rate under such section).

30 “(2) SECRETARIAL FLEXIBILITY.—The Secretary shall
 31 establish by regulation reasonable limits on the categories
 32 of eligible items and services for which a prior determina-
 33 tion of coverage may be requested under this subsection. In
 34 establishing such limits, the Secretary may consider the
 35 dollar amount involved with respect to the item or service,
 36 administrative costs and burdens, and other relevant fac-
 37 tors.

1 “(3) REQUEST FOR PRIOR DETERMINATION.—

2 “(A) IN GENERAL.—Subject to paragraph (2),
3 under the process established under this subsection an
4 eligible requester may submit to the contractor a re-
5 quest for a determination, before the furnishing of an
6 eligible item or service involved as to whether the item
7 or service is covered under this title consistent with the
8 applicable requirements of section 1862(a)(1)(A) (relat-
9 ing to medical necessity).

10 “(B) ACCOMPANYING DOCUMENTATION.—The Sec-
11 retary may require that the request be accompanied by
12 a description of the item or service, supporting docu-
13 mentation relating to the medical necessity for the item
14 or service, and any other appropriate documentation.
15 In the case of a request submitted by an eligible re-
16 quester who is described in paragraph (1)(B)(ii), the
17 Secretary may require that the request also be accom-
18 panied by a copy of the advance beneficiary notice in-
19 volved.

20 “(4) RESPONSE TO REQUEST.—

21 “(A) IN GENERAL.—Under such process, the con-
22 tractor shall provide the eligible requester with written
23 notice of a determination as to whether—

24 “(i) the item or service is so covered;

25 “(ii) the item or service is not so covered; or

26 “(iii) the contractor lacks sufficient informa-
27 tion to make a coverage determination.

28 If the contractor makes the determination described in
29 clause (iii), the contractor shall include in the notice a
30 description of the additional information required to
31 make the coverage determination.

32 “(B) DEADLINE TO RESPOND.—Such notice shall
33 be provided within the same time period as the time pe-
34 riod applicable to the contractor providing notice of ini-
35 tial determinations on a claim for benefits under sub-
36 section (a)(2)(A).

“(C) INFORMING BENEFICIARY IN CASE OF PHYSICIAN REQUEST.—In the case of a request in which an eligible requester is not the individual described in paragraph (1)(B)(ii), the process shall provide that the individual to whom the item or service is proposed to be furnished shall be informed of any determination described in clause (ii) (relating to a determination of non-coverage) and the right (referred to in paragraph (6)(B)) to obtain the item or service and have a claim submitted for the item or service.

“(5) EFFECT OF DETERMINATIONS.—

“(A) BINDING NATURE OF POSITIVE DETERMINATION.—If the contractor makes the determination described in paragraph (4)(A)(i), such determination shall be binding on the contractor in the absence of fraud or evidence of misrepresentation of facts presented to the contractor.

“(B) NOTICE AND RIGHT TO REDETERMINATION IN CASE OF A DENIAL.—

“(i) IN GENERAL.—If the contractor makes the determination described in paragraph (4)(A)(ii)—

“(I) the eligible requester has the right to a redetermination by the contractor on the determination that the item or service is not so covered; and

“(II) the contractor shall include in notice under paragraph (4)(A) a brief explanation of the basis for the determination, including on what national or local coverage or noncoverage determination (if any) the determination is based, and the right to such a redetermination.

“(ii) DEADLINE FOR REDETERMINATIONS.—The contractor shall complete and provide notice of such redetermination within the same time period as the time period applicable to the contractor pro-

viding notice of redeterminations relating to a claim for benefits under subsection (a)(3)(C)(ii).

“(6) LIMITATION ON FURTHER REVIEW.—

“(A) IN GENERAL.—Contractor determinations described in paragraph (4)(A)(ii) or (4)(A)(iii) (and redeterminations made under paragraph (5)(B)), relating to pre-service claims are not subject to further administrative appeal or judicial review under this section or otherwise.

“(B) DECISION NOT TO SEEK PRIOR DETERMINATION OR NEGATIVE DETERMINATION DOES NOT IMPACT RIGHT TO OBTAIN SERVICES, SEEK REIMBURSEMENT, OR APPEAL RIGHTS.—Nothing in this subsection shall be construed as affecting the right of an individual who—

“(i) decides not to seek a prior determination under this subsection with respect to items or services; or

“(ii) seeks such a determination and has received a determination described in paragraph (4)(A)(ii),

from receiving (and submitting a claim for) such items services and from obtaining administrative or judicial review respecting such claim under the other applicable provisions of this section. Failure to seek a prior determination under this subsection with respect to items and services shall not be taken into account in such administrative or judicial review.

“(C) NO PRIOR DETERMINATION AFTER RECEIPT OF SERVICES.—Once an individual is provided items and services, there shall be no prior determination under this subsection with respect to such items or services.”.

(b) EFFECTIVE DATE; TRANSITION.—

(1) EFFECTIVE DATE.—The Secretary shall establish the prior determination process under the amendment made by subsection (a) in such a manner as to provide for

1 the acceptance of requests for determinations under such
 2 process filed not later than 18 months after the date of the
 3 enactment of this Act.

4 (2) TRANSITION.—During the period in which the
 5 amendment made by subsection (a) has become effective
 6 but contracts are not provided under section 1874A of the
 7 Social Security Act with medicare administrative contrac-
 8 tors, any reference in section 1869(g) of such Act (as
 9 added by such amendment) to such a contractor is deemed
 10 a reference to a fiscal intermediary or carrier with an
 11 agreement under section 1816, or contract under section
 12 1842, respectively, of such Act.

13 (3) LIMITATION ON APPLICATION TO SGR.—For pur-
 14 poses of applying section 1848(f)(2)(D) of the Social Secu-
 15 rity Act (42 U.S.C. 1395w-4(f)(2)(D)), the amendment
 16 made by subsection (a) shall not be considered to be a
 17 change in law or regulation.

18 (c) PROVISIONS RELATING TO ADVANCE BENEFICIARY
 19 NOTICES; REPORT ON PRIOR DETERMINATION PROCESS.—

20 (1) DATA COLLECTION.—The Secretary shall establish
 21 a process for the collection of information on the instances
 22 in which an advance beneficiary notice (as defined in para-
 23 graph (4)) has been provided and on instances in which a
 24 beneficiary indicates on such a notice that the beneficiary
 25 does not intend to seek to have the item or service that is
 26 the subject of the notice furnished.

27 (2) OUTREACH AND EDUCATION.—The Secretary shall
 28 establish a program of outreach and education for bene-
 29 ficiaries and providers of services and other persons on the
 30 appropriate use of advance beneficiary notices and coverage
 31 policies under the medicare program.

32 (3) GAO REPORT REPORT ON USE OF ADVANCE BENE-
 33 FICIARY NOTICES.—Not later than 18 months after the
 34 date on which section 1869(g) of the Social Security Act
 35 (as added by subsection (a)) takes effect, the Comptroller
 36 General of the United States shall submit to Congress a re-
 37 port on the use of advance beneficiary notices under title

XVIII of such Act. Such report shall include information concerning the providers of services and other persons that have provided such notices and the response of beneficiaries to such notices.

(4) GAO REPORT ON USE OF PRIOR DETERMINATION PROCESS.—Not later than 18 months after the date on which section 1869(g) of the Social Security Act (as added by subsection (a)) takes effect, the Comptroller General of the United States shall submit to Congress a report on the use of the prior determination process under such section. Such report shall include—

(A) information concerning the types of procedures for which a prior determination has been sought, determinations made under the process, and changes in receipt of services resulting from the application of such process; and

(B) an evaluation of whether the process was useful for physicians (and other suppliers) and beneficiaries, whether it was timely, and whether the amount of information required was burdensome to physicians and beneficiaries.

(5) ADVANCE BENEFICIARY NOTICE DEFINED.—In this subsection, the term “advance beneficiary notice” means a written notice provided under section 1879(a) of the Social Security Act (42 U.S.C. 1395pp(a)) to an individual entitled to benefits under part A or B of title XVIII of such Act before items or services are furnished under such part in cases where a provider of services or other person that would furnish the item or service believes that payment will not be made for some or all of such items or services under such title.

Subtitle E—Miscellaneous Provisions

SEC. 841. POLICY DEVELOPMENT REGARDING EVALUATION AND MANAGEMENT (E & M) DOCUMENTATION GUIDELINES.

(a) IN GENERAL.—The Secretary may not implement any new documentation guidelines for evaluation and management

1 physician services under the title XVIII of the Social Security
 2 Act on or after the date of the enactment of this Act unless
 3 the Secretary—

4 (1) has developed the guidelines in collaboration with
 5 practicing physicians (including both generalists and spe-
 6 cialists) and provided for an assessment of the proposed
 7 guidelines by the physician community;

8 (2) has established a plan that contains specific goals,
 9 including a schedule, for improving the use of such guide-
 10 lines;

11 (3) has conducted appropriate and representative pilot
 12 projects under subsection (b) to test modifications to the
 13 evaluation and management documentation guidelines;

14 (4) finds that the objectives described in subsection (c)
 15 will be met in the implementation of such guidelines; and

16 (5) has established, and is implementing, a program to
 17 educate physicians on the use of such guidelines and that
 18 includes appropriate outreach.

19 The Secretary shall make changes to the manner in which ex-
 20 isting evaluation and management documentation guidelines
 21 are implemented to reduce paperwork burdens on physicians.

22 (b) PILOT PROJECTS TO TEST EVALUATION AND MAN-
 23 AGEMENT DOCUMENTATION GUIDELINES.—

24 (1) IN GENERAL.—The Secretary shall conduct under
 25 this subsection appropriate and representative pilot projects
 26 to test new evaluation and management documentation
 27 guidelines referred to in subsection (a).

28 (2) LENGTH AND CONSULTATION.—Each pilot project
 29 under this subsection shall—

30 (A) be voluntary;

31 (B) be of sufficient length as determined by the
 32 Secretary to allow for preparatory physician and medi-
 33 care contractor education, analysis, and use and assess-
 34 ment of potential evaluation and management guide-
 35 lines; and

36 (C) be conducted, in development and throughout
 37 the planning and operational stages of the project, in

consultation with practicing physicians (including both generalists and specialists).

(3) RANGE OF PILOT PROJECTS.—Of the pilot projects conducted under this subsection—

(A) at least one shall focus on a peer review method by physicians (not employed by a medicare contractor) which evaluates medical record information for claims submitted by physicians identified as statistical outliers relative to definitions published in the Current Procedures Terminology (CPT) code book of the American Medical Association;

(B) at least one shall focus on an alternative method to detailed guidelines based on physician documentation of face to face encounter time with a patient;

(C) at least one shall be conducted for services furnished in a rural area and at least one for services furnished outside such an area; and

(D) at least one shall be conducted in a setting where physicians bill under physicians' services in teaching settings and at least one shall be conducted in a setting other than a teaching setting.

(4) BANNING OF TARGETING OF PILOT PROJECT PARTICIPANTS.—Data collected under this subsection shall not be used as the basis for overpayment demands or post-payment audits. Such limitation applies only to claims filed as part of the pilot project and lasts only for the duration of the pilot project and only as long as the provider is a participant in the pilot project.

(5) STUDY OF IMPACT.—Each pilot project shall examine the effect of the new evaluation and management documentation guidelines on—

(A) different types of physician practices, including those with fewer than 10 full-time-equivalent employees (including physicians); and

(B) the costs of physician compliance, including education, implementation, auditing, and monitoring.

1 (6) PERIODIC REPORTS.—The Secretary shall submit
2 to Congress periodic reports on the pilot projects under this
3 subsection.

4 (c) OBJECTIVES FOR EVALUATION AND MANAGEMENT
5 GUIDELINES.—The objectives for modified evaluation and man-
6 agement documentation guidelines developed by the Secretary
7 shall be to—

8 (1) identify clinically relevant documentation needed to
9 code accurately and assess coding levels accurately;

10 (2) decrease the level of non-clinically pertinent and
11 burdensome documentation time and content in the physi-
12 cian's medical record;

13 (3) increase accuracy by reviewers; and

14 (4) educate both physicians and reviewers.

15 (d) STUDY OF SIMPLER, ALTERNATIVE SYSTEMS OF DOC-
16 UMENTATION FOR PHYSICIAN CLAIMS.—

17 (1) STUDY.—The Secretary shall carry out a study of
18 the matters described in paragraph (2).

19 (2) MATTERS DESCRIBED.—The matters referred to in
20 paragraph (1) are—

21 (A) the development of a simpler, alternative sys-
22 tem of requirements for documentation accompanying
23 claims for evaluation and management physician serv-
24 ices for which payment is made under title XVIII of
25 the Social Security Act; and

26 (B) consideration of systems other than current
27 coding and documentation requirements for payment
28 for such physician services.

29 (3) CONSULTATION WITH PRACTICING PHYSICIANS.—
30 In designing and carrying out the study under paragraph
31 (1), the Secretary shall consult with practicing physicians,
32 including physicians who are part of group practices and
33 including both generalists and specialists.

34 (4) APPLICATION OF HIPAA UNIFORM CODING RE-
35 QUIREMENTS.—In developing an alternative system under
36 paragraph (2), the Secretary shall consider requirements of

administrative simplification under part C of title XI of the Social Security Act.

(5) REPORT TO CONGRESS.—(A) Not later than October 1, 2004, the Secretary shall submit to Congress a report on the results of the study conducted under paragraph (1).

(B) The Medicare Payment Advisory Commission shall conduct an analysis of the results of the study included in the report under subparagraph (A) and shall submit a report on such analysis to Congress.

(e) STUDY ON APPROPRIATE CODING OF CERTAIN EXTENDED OFFICE VISITS.—The Secretary shall conduct a study of the appropriateness of coding in cases of extended office visits in which there is no diagnosis made. Not later than October 1, 2004, the Secretary shall submit a report to Congress on such study and shall include recommendations on how to code appropriately for such visits in a manner that takes into account the amount of time the physician spent with the patient.

(f) DEFINITIONS.—In this section—

(1) the term “rural area” has the meaning given that term in section 1886(d)(2)(D) of the Social Security Act, 42 U.S.C. 1395ww(d)(2)(D); and

(2) the term “teaching settings” are those settings described in section 415.150 of title 42, Code of Federal Regulations.

SEC. 842. IMPROVEMENT IN OVERSIGHT OF TECHNOLOGY AND COVERAGE.

(a) IMPROVED COORDINATION BETWEEN FDA AND CMS ON COVERAGE OF BREAKTHROUGH MEDICAL DEVICES.—

(1) IN GENERAL.—Upon request by an applicant and to the extent feasible (as determined by the Secretary), the Secretary shall, in the case of a class III medical device that is subject to premarket approval under section 515 of the Federal Food, Drug, and Cosmetic Act, ensure the sharing of appropriate information from the review for application for premarket approval conducted by the Food

1 and Drug Administration for coverage decisions under title
2 XVIII of the Social Security Act.

3 (2) PUBLICATION OF PLAN.—Not later than 6 months
4 after the date of the enactment of this Act, the Secretary
5 shall submit to appropriate Committees of Congress a re-
6 port that contains the plan for improving such coordination
7 and for shortening the time lag between the premarket ap-
8 proval by the Food and Drug Administration and coding
9 and coverage decisions by the Centers for Medicare & Med-
10 icaid Services.

11 (3) CONSTRUCTION.—Nothing in this subsection shall
12 be construed as changing the criteria for coverage of a
13 medical device under title XVIII of the Social Security Act
14 nor premarket approval by the Food and Drug Administra-
15 tion and nothing in this subsection shall be construed to in-
16 crease premarket approval application requirements under
17 the Federal Food, Drug, and Cosmetic Act.

18 (b) COUNCIL FOR TECHNOLOGY AND INNOVATION.—Sec-
19 tion 1868 (42 U.S.C. 1395ee), as amended by section 821(a),
20 is amended by adding at the end the following new subsection:

21 “(c) COUNCIL FOR TECHNOLOGY AND INNOVATION.—

22 “(1) ESTABLISHMENT.—The Secretary shall establish
23 a Council for Technology and Innovation within the Cen-
24 ters for Medicare & Medicaid Services (in this section re-
25 ferred to as ‘CMS’).

26 “(2) COMPOSITION.—The Council shall be composed
27 of senior CMS staff and clinicians and shall be chaired by
28 the Executive Coordinator for Technology and Innovation
29 (appointed or designated under paragraph (4)).

30 “(3) DUTIES.—The Council shall coordinate the activi-
31 ties of coverage, coding, and payment processes under this
32 title with respect to new technologies and procedures, in-
33 cluding new drug therapies, and shall coordinate the ex-
34 change of information on new technologies between CMS
35 and other entities that make similar decisions.

36 “(4) EXECUTIVE COORDINATOR FOR TECHNOLOGY
37 AND INNOVATION.—The Secretary shall appoint (or des-

1 igrate) a noncareer appointee (as defined in section
 2 3132(a)(7) of title 5, United States Code) who shall serve
 3 as the Executive Coordinator for Technology and Innova-
 4 tion. Such executive coordinator shall report to the Admin-
 5 istrator of CMS, shall chair the Council, shall oversee the
 6 execution of its duties, and shall serve as a single point of
 7 contact for outside groups and entities regarding the cov-
 8 erage, coding, and payment processes under this title.”.

9 (c) GAO STUDY ON IMPROVEMENTS IN EXTERNAL DATA
 10 COLLECTION FOR USE IN THE MEDICARE INPATIENT PAY-
 11 MENT SYSTEM.—

12 (1) STUDY.—The Comptroller General of the United
 13 States shall conduct a study that analyzes which external
 14 data can be collected in a shorter time frame by the Cen-
 15 ters for Medicare & Medicaid Services for use in computing
 16 payments for inpatient hospital services. The study may in-
 17 clude an evaluation of the feasibility and appropriateness of
 18 using of quarterly samples or special surveys or any other
 19 methods. The study shall include an analysis of whether
 20 other executive agencies, such as the Bureau of Labor Sta-
 21 tistics in the Department of Commerce, are best suited to
 22 collect this information.

23 (2) REPORT.—By not later than October 1, 2003, the
 24 Comptroller General shall submit a report to Congress on
 25 the study under paragraph (1).

26 (d) IOM STUDY ON LOCAL COVERAGE DETERMINA-
 27 TIONS.—

28 (1) STUDY.—The Secretary shall enter into an ar-
 29 rangement with the Institute of Medicine of the National
 30 Academy of Sciences under which the Institute shall con-
 31 duct a study on local coverage determinations (including
 32 the application of local medical review policies) under the
 33 medicare program under title XVIII of the Social Security
 34 Act. Such study shall examine—

35 (A) the consistency of the definitions used in such
 36 determinations;

1 (B) the types of evidence on which such deter-
 2 minations are based, including medical and scientific
 3 evidence;

4 (C) the advantages and disadvantages of local cov-
 5 erage decisionmaking, including the flexibility it offers
 6 for ensuring timely patient access to new medical tech-
 7 nology for which data are still be collected;

8 (D) the manner in which the local coverage deter-
 9 mination process is used to develop data needed for a
 10 national coverage determination, including the need for
 11 collection of such data within a protocol and informed
 12 consent by individuals entitled to benefits under part A
 13 of title XVIII of the Social Security Act, or enrolled
 14 under part B of such title, or both; and

15 (E) the advantages and disadvantages of main-
 16 taining local medicare contractor advisory committees
 17 that can advise on local coverage decisions based on an
 18 open, collaborative public process.

19 (2) REPORT.—Such arrangement shall provide that
 20 the Institute shall submit to the Secretary a report on such
 21 study by not later than 3 years after the date of the enact-
 22 ment of this Act. The Secretary shall promptly transmit a
 23 copy of such report to Congress.

24 (e) METHODS FOR DETERMINING PAYMENT BASIS FOR
 25 NEW LAB TESTS.—Section 1833(h) (42 U.S.C. 1395l(h)) is
 26 amended by adding at the end the following:

27 “(8)(A) The Secretary shall establish by regulation proce-
 28 dures for determining the basis for, and amount of, payment
 29 under this subsection for any clinical diagnostic laboratory test
 30 with respect to which a new or substantially revised HCPCS
 31 code is assigned on or after January 1, 2004 (in this para-
 32 graph referred to as ‘new tests’).

33 “(B) Determinations under subparagraph (A) shall be
 34 made only after the Secretary—

35 “(i) makes available to the public (through an Internet
 36 site and other appropriate mechanisms) a list that includes

1 any such test for which establishment of a payment amount
2 under this subsection is being considered for a year;

3 “(ii) on the same day such list is made available,
4 causes to have published in the Federal Register notice of
5 a meeting to receive comments and recommendations (and
6 data on which recommendations are based) from the public
7 on the appropriate basis under this subsection for estab-
8 lishing payment amounts for the tests on such list;

9 “(iii) not less than 30 days after publication of such
10 notice convenes a meeting, that includes representatives of
11 officials of the Centers for Medicare & Medicaid Services
12 involved in determining payment amounts, to receive such
13 comments and recommendations (and data on which the
14 recommendations are based);

15 “(iv) taking into account the comments and rec-
16 ommendations (and accompanying data) received at such
17 meeting, develops and makes available to the public
18 (through an Internet site and other appropriate mecha-
19 nisms) a list of proposed determinations with respect to the
20 appropriate basis for establishing a payment amount under
21 this subsection for each such code, together with an expla-
22 nation of the reasons for each such determination, the data
23 on which the determinations are based, and a request for
24 public written comments on the proposed determination;
25 and

26 “(v) taking into account the comments received during
27 the public comment period, develops and makes available to
28 the public (through an Internet site and other appropriate
29 mechanisms) a list of final determinations of the payment
30 amounts for such tests under this subsection, together with
31 the rationale for each such determination, the data on
32 which the determinations are based, and responses to com-
33 ments and suggestions received from the public.

34 “(C) Under the procedures established pursuant to sub-
35 paragraph (A), the Secretary shall—

36 “(i) set forth the criteria for making determinations
37 under subparagraph (A); and

“(ii) make available to the public the data (other than proprietary data) considered in making such determinations.

“(D) The Secretary may convene such further public meetings to receive public comments on payment amounts for new tests under this subsection as the Secretary deems appropriate.

“(E) For purposes of this paragraph:

“(i) The term ‘HCPCS’ refers to the Health Care Procedure Coding System.

“(ii) A code shall be considered to be ‘substantially revised’ if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test).”.

SEC. 843. TREATMENT OF HOSPITALS FOR CERTAIN SERVICES UNDER MEDICARE SECONDARY PAYOR (MSP) PROVISIONS.

(a) IN GENERAL.—The Secretary shall not require a hospital (including a critical access hospital) to ask questions (or obtain information) relating to the application of section 1862(b) of the Social Security Act (relating to medicare secondary payor provisions) in the case of reference laboratory services described in subsection (b), if the Secretary does not impose such requirement in the case of such services furnished by an independent laboratory.

(b) REFERENCE LABORATORY SERVICES DESCRIBED.—Reference laboratory services described in this subsection are clinical laboratory diagnostic tests (or the interpretation of such tests, or both) furnished without a face-to-face encounter between the individual entitled to benefits under part A or enrolled under part B, or both, and the hospital involved and in which the hospital submits a claim only for such test or interpretation.

SEC. 844. EMTALA IMPROVEMENTS.

(a) PAYMENT FOR EMTALA-MANDATED SCREENING AND STABILIZATION SERVICES.—

(1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is amended by inserting after subsection (c) the following new subsection:

“(d) For purposes of subsection (a)(1)(A), in the case of any item or service that is required to be provided pursuant to section 1867 to an individual who is entitled to benefits under this title, determinations as to whether the item or service is reasonable and necessary shall be made on the basis of the information available to the treating physician or practitioner (including the patient’s presenting symptoms or complaint) at the time the item or service was ordered or furnished by the physician or practitioner (and not on the patient’s principal diagnosis). When making such determinations with respect to such an item or service, the Secretary shall not consider the frequency with which the item or service was provided to the patient before or after the time of the admission or visit.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to items and services furnished on or after January 1, 2003.

(b) NOTIFICATION OF PROVIDERS WHEN EMTALA INVESTIGATION CLOSED.—Section 1867(d) (42 U.S.C. 1395dd(d)) is amended by adding at the end the following new paragraph:

“(4) NOTICE UPON CLOSING AN INVESTIGATION.—The Secretary shall establish a procedure to notify hospitals and physicians when an investigation under this section is closed.”.

(c) PRIOR REVIEW BY PEER REVIEW ORGANIZATIONS IN EMTALA CASES INVOLVING TERMINATION OF PARTICIPATION.—

(1) IN GENERAL.—Section 1867(d)(3) (42 U.S.C. 1395dd(d)(3)) is amended—

(A) in the first sentence, by inserting “or in terminating a hospital’s participation under this title” after “in imposing sanctions under paragraph (1)”; and

(B) by adding at the end the following new sentences: “Except in the case in which a delay would

1 jeopardize the health or safety of individuals, the Sec-
 2 retary shall also request such a review before making
 3 a compliance determination as part of the process of
 4 terminating a hospital's participation under this title
 5 for violations related to the appropriateness of a med-
 6 ical screening examination, stabilizing treatment, or an
 7 appropriate transfer as required by this section, and
 8 shall provide a period of 5 days for such review. The
 9 Secretary shall provide a copy of the report on the or-
 10 ganization's report to the hospital or physician con-
 11 sistent with confidentiality requirements imposed on
 12 the organization under such part B.".

13 (2) EFFECTIVE DATE.—The amendments made by
 14 paragraph (1) shall apply to terminations of participation
 15 initiated on or after the date of the enactment of this Act.

16 **SEC. 845. EMERGENCY MEDICAL TREATMENT AND AC-**
 17 **TIVE LABOR ACT (EMTALA) TECHNICAL AD-**
 18 **VISORY GROUP.**

19 (a) ESTABLISHMENT.—The Secretary shall establish a
 20 Technical Advisory Group (in this section referred to as the
 21 “Advisory Group”) to review issues related to the Emergency
 22 Medical Treatment and Active Labor Act (EMTALA) and its
 23 implementation. In this section, the term “EMTALA” refers to
 24 the provisions of section 1867 of the Social Security Act (42
 25 U.S.C. 1395dd).

26 (b) MEMBERSHIP.—The Advisory Group shall be com-
 27 posed of 19 members, including the Administrator of the Cen-
 28 ters for Medicare & Medicaid Services and the Inspector Gen-
 29 eral of the Department of Health and Human Services and of
 30 which—

31 (1) 4 shall be representatives of hospitals, including at
 32 least one public hospital, that have experience with the ap-
 33 plication of EMTALA and at least 2 of which have not
 34 been cited for EMTALA violations;

35 (2) 7 shall be practicing physicians drawn from the
 36 fields of emergency medicine, cardiology or cardiothoracic
 37 surgery, orthopedic surgery, neurosurgery, obstetrics-gyne-

cology, and psychiatry, with not more than one physician from any particular field;

(3) 2 shall represent patients;

(4) 2 shall be staff involved in EMTALA investigations from different regional offices of the Centers for Medicare & Medicaid Services; and

(5) 1 shall be from a State survey office involved in EMTALA investigations and 1 shall be from a peer review organization, both of whom shall be from areas other than the regions represented under paragraph (4).

In selecting members described in paragraphs (1) through (3), the Secretary shall consider qualified individuals nominated by organizations representing providers and patients.

(c) GENERAL RESPONSIBILITIES.—The Advisory Group—

(1) shall review EMTALA regulations;

(2) may provide advice and recommendations to the Secretary with respect to those regulations and their application to hospitals and physicians;

(3) shall solicit comments and recommendations from hospitals, physicians, and the public regarding the implementation of such regulations; and

(4) may disseminate information on the application of such regulations to hospitals, physicians, and the public.

(d) ADMINISTRATIVE MATTERS.—

(1) CHAIRPERSON.—The members of the Advisory Group shall elect a member to serve as chairperson of the Advisory Group for the life of the Advisory Group.

(2) MEETINGS.—The Advisory Group shall first meet at the direction of the Secretary. The Advisory Group shall then meet twice per year and at such other times as the Advisory Group may provide.

(e) TERMINATION.—The Advisory Group shall terminate 30 months after the date of its first meeting.

(f) WAIVER OF ADMINISTRATIVE LIMITATION.—The Secretary shall establish the Advisory Group notwithstanding any limitation that may apply to the number of advisory committees

that may be established (within the Department of Health and Human Services or otherwise).

SEC. 846. AUTHORIZING USE OF ARRANGEMENTS WITH OTHER HOSPICE PROGRAMS TO PROVIDE CORE HOSPICE SERVICES IN CERTAIN CIRCUMSTANCES.

(a) IN GENERAL.—Section 1861(dd)(5) (42 U.S.C. 1395x(dd)(5)) is amended by adding at the end the following new subparagraph:

“(D) In extraordinary, exigent, or other non-routine circumstances, such as unanticipated periods of high patient loads, staffing shortages due to illness or other events, or temporary travel of a patient outside a hospice program’s service area, a hospice program may enter into arrangements with another hospice program for the provision by that other program of services described in paragraph (2)(A)(ii)(I). The provisions of paragraph (2)(A)(ii)(II) shall apply with respect to the services provided under such arrangements.”.

(b) CONFORMING PAYMENT PROVISION.—Section 1814(i) (42 U.S.C. 1395f(i)) is amended by adding at the end the following new paragraph:

“(4) In the case of hospice care provided by a hospice program under arrangements under section 1861(dd)(5)(D) made by another hospice program, the hospice program that made the arrangements shall bill and be paid for the hospice care.”.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to hospice care provided on or after the date of the enactment of this Act.

SEC. 847. APPLICATION OF OSHA BLOODBORNE PATHOGENS STANDARD TO CERTAIN HOSPITALS.

(a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is amended—

(1) in subsection (a)(1)—

(A) in subparagraph (R), by striking “and” at the end;

(B) in subparagraph (S), by striking the period at the end and inserting “, and”; and

(C) by inserting after subparagraph (S) the following new subparagraph:

“(T) in the case of hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970, to comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations (or as subsequently redesignated).”; and

(B) by adding at the end of subsection (b) the following new paragraph:

“(4)(A) A hospital that fails to comply with the requirement of subsection (a)(1)(T) (relating to the Bloodborne Pathogens standard) is subject to a civil money penalty in an amount described in subparagraph (B), but is not subject to termination of an agreement under this section.

“(B) The amount referred to in subparagraph (A) is an amount that is similar to the amount of civil penalties that may be imposed under section 17 of the Occupational Safety and Health Act of 1970 for a violation of the Bloodborne Pathogens standard referred to in subsection (a)(1)(T) by a hospital that is subject to the provisions of such Act.

“(C) A civil money penalty under this paragraph shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.”.

(b) EFFECTIVE DATE.—The amendments made by this subsection (a) shall apply to hospitals as of July 1, 2003.

SEC. 848. BIPA-RELATED TECHNICAL AMENDMENTS AND CORRECTIONS.

(a) TECHNICAL AMENDMENTS RELATING TO ADVISORY COMMITTEE UNDER BIPA SECTION 522.—(1) Subsection (i) of section 1114 (42 U.S.C. 1314)—

(A) is transferred to section 1862 and added at the end of such section; and

(B) is redesignated as subsection (j).

(2) Section 1862 (42 U.S.C. 1395y) is amended—

(A) in the last sentence of subsection (a), by striking “established under section 1114(f)”;

(B) in subsection (j), as so transferred and redesignated—

(i) by striking “under subsection (f)” and

(ii) by striking “section 1862(a)(1)” and inserting “subsection (a)(1)”.

(b) TERMINOLOGY CORRECTIONS.—(1) Section 1869(c)(3)(I)(ii) (42 U.S.C. 1395ff(c)(3)(I)(ii)), as amended by section 521 of BIPA, is amended—

(A) in subclause (III), by striking “policy” and inserting “determination”; and

(B) in subclause (IV), by striking “medical review — policies” and inserting “coverage determinations”.

(2) Section 1852(a)(2)(C) (42 U.S.C. 1395w-22(a)(2)(C)) is amended by striking “policy” and “POLICY” and inserting “determination” each place it appears and “DETERMINATION”, respectively.

(c) REFERENCE CORRECTIONS.—Section 1869(f)(4) (42 U.S.C. 1395ff(f)(4)), as added by section 522 of BIPA, is amended—

(1) in subparagraph (A)(iv), by striking “subclause –(I), (II), or (III)” and inserting “clause (i), (ii), or (iii)”;

(2) in subparagraph (B), by striking “clause (i)(IV)” and “clause (i)(III)” and inserting “subparagraph (A)(iv)” and “subparagraph (A)(iii)”, respectively; and

(3) in subparagraph (C), by striking “clause (i)”, “subclause (IV)” and “subparagraph (A)” and inserting “subparagraph (A)”, “clause (iv)” and “paragraph (1)(A)”, respectively each place it appears.

(d) OTHER CORRECTIONS.—Effective as if included in the enactment of section 521(c) of BIPA, section 1154(e) (42 U.S.C. 1320c-3(e)) is amended by striking paragraph (5).

(e) EFFECTIVE DATE.—Except as otherwise provided, the amendments made by this section shall be effective as if included in the enactment of BIPA.

SEC. 849. CONFORMING AUTHORITY TO WAIVE A PROGRAM EXCLUSION.

The first sentence of section 1128(c)(3)(B) (42 U.S.C. 1320a–7(c)(3)(B)) is amended to read as follows: “Subject to subparagraph (G), in the case of an exclusion under subsection (a), the minimum period of exclusion shall be not less than five years, except that, upon the request of the administrator of a Federal health care program (as defined in section 1128B(f)) who determines that the exclusion would impose a hardship on individuals entitled to benefits under part A of title XVIII or enrolled under part B of such title, or both, the Secretary may waive the exclusion under subsection (a)(1), (a)(3), or (a)(4) with respect to that program in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in a community.”.

SEC. 850. TREATMENT OF CERTAIN DENTAL CLAIMS.

(a) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is amended by inserting after subsection (c) the following new subsection:

“(d)(1) Subject to paragraph (2), a group health plan (as defined in subsection (a)(1)(A)(v)) providing supplemental or secondary coverage to individuals also entitled to services under this title shall not require a medicare claims determination under this title for dental benefits specifically excluded under subsection (a)(12) as a condition of making a claims determination for such benefits under the group health plan.

“(2) A group health plan may require a claims determination under this title in cases involving or appearing to involve inpatient dental hospital services or dental services expressly covered under this title pursuant to actions taken by the Secretary.”.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date that is 60 days after the date of the enactment of this Act.

**SEC. 851. ANNUAL PUBLICATION OF LIST OF NATIONAL
COVERAGE DETERMINATIONS.**

The Secretary shall provide, in an appropriate annual publication available to the public, a list of national coverage determinations made under title XVIII of the Social Security Act in the previous year and information on how to get more information with respect to such determinations.

**TITLE IX—MEDICAID, PUBLIC
HEALTH, AND OTHER HEALTH
PROVISIONS**

Subtitle A—Medicaid Provisions

**SEC. 901. NATIONAL BIPARTISAN COMMISSION ON THE
FUTURE OF MEDICAID.**

(a) **ESTABLISHMENT.**—There is established a commission to be known as the National Bipartisan Commission on the Future of Medicaid (in this section referred to as the “Commission”).

(b) **DUTIES OF THE COMMISSION.**—The Commission shall—

(1) review and analyze the long-term financial condition of the medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.);

(2) identify the factors that are causing, and the consequences of, increases in costs under the medicaid program, including—

(A) the impact of these cost increases upon State budgets, funding for other State programs, and levels of State taxes necessary to fund growing expenditures under the medicaid program;

(B) the financial obligations of the Federal government arising from the Federal matching requirement for expenditures under the medicaid program; and

(C) the size and scope of the current program and how the program has evolved over time;

(3) analyze potential policies that will ensure both the financial integrity of the medicaid program and the provision of appropriate benefits under such program;

(4) make recommendations for establishing incentives and structures to promote enhanced efficiencies and ways of encouraging innovative State policies under the medicaid program;

(5) make recommendations for establishing the appropriate balance between benefits covered, payments to providers, State and Federal contributions and, where appropriate, recipient cost-sharing obligations;

(6) make recommendations on the impact of promoting increased utilization of competitive, private enterprise models to contain program cost growth, through enhanced utilization of private plans, pharmacy benefit managers, and other methods currently being used to contain private sector health-care costs;

(7) make recommendations on the financing of prescription drug benefits currently covered under medicaid programs, including analysis of the current Federal manufacturer rebate program, its impact upon both private market prices as well as those paid by other government purchasers, recent State efforts to negotiate additional supplemental manufacturer rebates and the ability of pharmacy benefit managers to lower drug costs;

(8) review and analyze such other matters relating to the medicaid program as the Commission deems appropriate; and

(9) analyze the impact of impending demographic changes upon medicaid benefits, including long term care services, and make recommendations for how best to appropriately divide State and Federal responsibilities for funding these benefits.

(c) MEMBERSHIP.—

(1) NUMBER AND APPOINTMENT.—The Commission shall be composed of 17 members, of whom—

(A) four shall be appointed by the President;

(B) six shall be appointed by the Majority Leader of the Senate, in consultation with the Minority Leader of the Senate, of whom not more than 4 shall be of the same political party;

(C) six shall be appointed by the Speaker of the House of Representatives, in consultation with the Minority Leader of the House of Representatives, of whom not more than 4 shall be of the same political party; and

(D) one, who shall serve as Chairman of the Commission, appointed jointly by the President, Majority Leader of the Senate, and the Speaker of the House of Representatives.

(2) DEADLINE FOR APPOINTMENT.—Members of the Commission shall be appointed by not later than December 1, 2002.

(3) TERMS OF APPOINTMENT.—The term of any appointment under paragraph (1) to the Commission shall be for the life of the Commission.

(4) MEETINGS.—The Commission shall meet at the call of its Chairman or a majority of its members.

(5) QUORUM.—A quorum shall consist of 8 members of the Commission, except that 4 members may conduct a hearing under subsection (e).

(6) VACANCIES.—A vacancy on the Commission shall be filled in the same manner in which the original appointment was made not later than 30 days after the Commission is given notice of the vacancy and shall not affect the power of the remaining members to execute the duties of the Commission.

(7) COMPENSATION.—Members of the Commission shall receive no additional pay, allowances, or benefits by reason of their service on the Commission.

(8) EXPENSES.—Each member of the Commission shall receive travel expenses and per diem in lieu of subsistence in accordance with sections 5702 and 5703 of title 5, United States Code.

(d) STAFF AND SUPPORT SERVICES.—

(1) EXECUTIVE DIRECTOR.—

(A) APPOINTMENT.—The Chairman shall appoint an executive director of the Commission.

(B) COMPENSATION.—The executive director shall be paid the rate of basic pay for level V of the Executive Schedule.

(2) STAFF.—With the approval of the Commission, the executive director may appoint such personnel as the executive director considers appropriate.

(3) APPLICABILITY OF CIVIL SERVICE LAWS.—The staff of the Commission shall be appointed without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title (relating to classification and General Schedule pay rates).

(4) EXPERTS AND CONSULTANTS.—With the approval of the Commission, the executive director may procure temporary and intermittent services under section 3109(b) of title 5, United States Code.

(5) PHYSICAL FACILITIES.—The Administrator of the General Services Administration shall locate suitable office space for the operation of the Commission. The facilities shall serve as the headquarters of the Commission and shall include all necessary equipment and incidentals required for the proper functioning of the Commission.

(e) POWERS OF COMMISSION.—

(1) HEARINGS AND OTHER ACTIVITIES.—For the purpose of carrying out its duties, the Commission may hold such hearings and undertake such other activities as the Commission determines to be necessary to carry out its duties.

(2) STUDIES BY GAO.—Upon the request of the Commission, the Comptroller General shall conduct such studies or investigations as the Commission determines to be necessary to carry out its duties.

1 (3) COST ESTIMATES BY CONGRESSIONAL BUDGET OF-
2 FICE AND OFFICE OF THE CHIEF ACTUARY OF HCFA.—

3 (A) The Director of the Congressional Budget Of-
4 fice or the Chief Actuary of the Centers for Medicare
5 & Medicaid Services, or both, shall provide to the Com-
6 mission, upon the request of the Commission, such cost
7 estimates as the Commission determines to be nec-
8 essary to carry out its duties.

9 (B) The Commission shall reimburse the Director
10 of the Congressional Budget Office for expenses relat-
11 ing to the employment in the office of the Director of
12 such additional staff as may be necessary for the Direc-
13 tor to comply with requests by the Commission under
14 subparagraph (A).

15 (4) DETAIL OF FEDERAL EMPLOYEES.—Upon the re-
16 quest of the Commission, the head of any Federal agency
17 is authorized to detail, without reimbursement, any of the
18 personnel of such agency to the Commission to assist the
19 Commission in carrying out its duties. Any such detail shall
20 not interrupt or otherwise affect the civil service status or
21 privileges of the Federal employee.

22 (5) TECHNICAL ASSISTANCE.—Upon the request of the
23 Commission, the head of a Federal agency shall provide
24 such technical assistance to the Commission as the Com-
25 mission determines to be necessary to carry out its duties.

26 (6) USE OF MAILS.—The Commission may use the
27 United States mails in the same manner and under the
28 same conditions as Federal agencies and shall, for purposes
29 of the frank, be considered a commission of Congress as
30 described in section 3215 of title 39, United States Code.

31 (7) OBTAINING INFORMATION.—The Commission may
32 secure directly from any Federal agency information nec-
33 essary to enable it to carry out its duties, if the information
34 may be disclosed under section 552 of title 5, United States
35 Code. Upon request of the Chairman of the Commission,
36 the head of such agency shall furnish such information to
37 the Commission.

(8) ADMINISTRATIVE SUPPORT SERVICES.—Upon the request of the Commission, the Administrator of General Services shall provide to the Commission on a reimbursable basis such administrative support services as the Commission may request.

(9) PRINTING.—For purposes of costs relating to printing and binding, including the cost of personnel detailed from the Government Printing Office, the Commission shall be deemed to be a committee of the Congress.

(f) REPORT.—Not later than March 1, 2004, the Commission shall submit a report to the President and Congress which shall contain a detailed statement of only those recommendations, findings, and conclusions of the Commission.

(g) TERMINATION.—The Commission shall terminate 30 days after the date of submission of the report required in subsection (f).

(h) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated \$1,500,000 to carry out this section.

SEC. 902. GAO STUDY ON MEDICAID DRUG PAYMENT SYSTEM.

(a) STUDY.—The Comptroller General of the United States shall conduct a study on the reimbursement under the medicaid program for covered outpatient drugs. Such study shall examine—

(1) the extent to which such reimbursements for a drug exceed the acquisition costs for that drug;

(2) the services and resources associated with dispensing a prescription and any additional payments available to compensate for expenses for these services and resources; and

(3) efforts undertaken by States to change the levels of such reimbursement and the price data they use in effecting such change.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under subsection (a)

and shall include in such report such recommendations for changes for legislative or administrative action regarding Medicaid reimbursement methodologies for outpatient prescription drugs, and their application to the Medicare program, as the Comptroller General deems appropriate.

Subtitle B—Internet Pharmacies

SEC. 911. FINDINGS.

The Congress finds as follows:

(1) Legitimate Internet sellers of prescription drugs can offer substantial benefits to consumers. These potential benefits include convenience, privacy, valuable information, competitive prices, and personalized services.

(2) Unlawful Internet sellers of prescription drugs may dispense inappropriate, contaminated, counterfeit, or subpotent prescription drugs that could put at risk the health and safety of consumers.

(3) Unlawful Internet sellers have exposed consumers to significant health risks by knowingly filling invalid prescriptions, such as prescriptions based solely on an online questionnaire, or by dispensing prescription drugs without any prescription.

(4) Consumers may have difficulty distinguishing legitimate from unlawful Internet sellers, as well as foreign from domestic Internet sellers, of prescription drugs.

SEC. 912. AMENDMENT TO FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 503A the following:

“SEC. 503B. INTERNET PRESCRIPTION DRUG SALES.

“(a) DEFINITIONS.—For purposes of this section:

“(1) CONSUMER.—The term ‘consumer’ means a person (other than an entity licensed or otherwise authorized under Federal or State law as a pharmacy or to dispense or distribute prescription drugs) that purchases or seeks to purchase prescription drugs through the Internet.

1 “(2) HOME PAGE.—The term ‘home page’ means the
2 entry point or main web page for an Internet site.

3 “(3) INTERNET.—The term ‘Internet’ means collec-
4 tively the myriad of computer and telecommunications fa-
5 cilities, including equipment and operating software, which
6 comprise the interconnected worldwide network of networks
7 that employ the Transmission Control Protocol/Internet
8 Protocol, or any predecessor or successor protocols to such
9 protocol, to communicate information of all kinds by wire
10 or radio, including electronic mail.

11 “(4) INTERSTATE INTERNET SELLER.—

12 “(A) IN GENERAL.—The term ‘interstate Internet
13 seller’ means a person whether in the United States or
14 abroad, that engages in, offers to engage in, or causes
15 the delivery or sale of a prescription drug through the
16 Internet and has such drug delivered directly to the
17 consumer via the Postal Service, or any private or com-
18 mercial interstate carrier to a consumer in the United
19 States who is residing in a State other than the State
20 in which the seller’s place of business is located. This
21 definition excludes a person who only delivers a pre-
22 scription drug to a consumer, such as an interstate car-
23 rier service.

24 “(B) EXEMPTION.—With respect to the consumer
25 involved, the term ‘interstate Internet seller’ does not
26 include a person described in subparagraph (A) whose
27 place of business is located within 75 miles of the con-
28 sumer.

29 “(5) LINK.—The term ‘link’ means either a textual or
30 graphical marker on a web page that, when clicked on,
31 takes the consumer to another part of the Internet, such
32 as to another web page or a different area on the same web
33 page, or from an electronic message to a web page.

34 “(6) PHARMACY.—The term ‘pharmacy’ means any
35 place licensed or otherwise authorized as a pharmacy under
36 State law.

“(7) PRESCRIBER.—The term ‘prescriber’ means an individual, licensed or otherwise authorized under applicable Federal and State law to issue prescriptions for prescription drugs.

“(8) PRESCRIPTION DRUG.—The term ‘prescription drug’ means a drug under section 503(b)(1).

“(9) VALID PRESCRIPTION.—The term ‘valid prescription’ means a prescription that meets the requirements of section 503(b)(1) and other applicable Federal and State law.

“(10) WEB SITE; SITE.—The terms ‘web site’ and ‘site’ mean a specific location on the Internet that is determined by Internet protocol numbers or by a domain name.

“(b) REQUIREMENTS FOR INTERSTATE INTERNET SELLERS.—

“(1) IN GENERAL.—Each interstate Internet seller shall comply with the requirements of this subsection with respect to the sale of, or the offer to sell, prescription drugs through the Internet and shall at all times display on its web site information in accordance with paragraph (2).

“(2) WEB SITE DISCLOSURE INFORMATION.—An interstate Internet seller shall post in a visible and clear manner (as determined by regulation) on the home page of its web site, or on a page directly linked to such home page—

“(A) the street address of the interstate Internet seller’s place of business, and the telephone number of such place of business;

“(B) each State in which the interstate Internet seller is licensed or otherwise authorized as a pharmacy, or if the interstate Internet seller is not licensed or otherwise authorized by a State as a pharmacy, each State in which the interstate Internet seller is licensed or otherwise authorized to dispense prescription drugs, and the type of State license or authorization;

“(C) in the case of an interstate Internet seller that makes referrals to or solicits on behalf of a prescriber, the name of each prescriber, the street address

1 of each such prescriber's place of business, the tele-
 2 phone number of such place of business, each State in
 3 which each such prescriber is licensed or otherwise au-
 4 thorized to prescribe prescription drugs, and the type
 5 of such license or authorization; and

6 “(D) a statement that the interstate Internet sell-
 7 er will dispense prescription drugs only upon a valid
 8 prescription.

9 “(3) DATE OF POSTING.—Information required to be
 10 posted under paragraph (2) shall be posted by an interstate
 11 Internet seller—

12 “(A) not later than 90 days after the effective date
 13 of this section if the web site of such seller is in oper-
 14 ation as of such date; or

15 “(B) on the date of the first day of operation of
 16 such seller's web site if such site goes into operation
 17 after such date.

18 “(4) QUALIFYING STATEMENTS.—An interstate Inter-
 19 net seller shall not indicate in any manner that posting dis-
 20 closure information on its web site signifies that the Fed-
 21 eral Government has made any determination on the legit-
 22 imacy of the interstate Internet seller or its business.

23 “(5) DISCLOSURE TO STATE LICENSING BOARDS.—An
 24 interstate Internet seller licensed or otherwise authorized to
 25 dispense prescription drugs in accordance with applicable
 26 State law shall notify each State entity that granted such
 27 licensure or authorization that it is an interstate Internet
 28 seller, the name of its business, the Internet address of its
 29 business, the street address of its place of business, and the
 30 telephone number of such place of business.

31 “(6) REGULATIONS.—The Secretary is authorized to
 32 promulgate such regulations as are necessary to carry out
 33 the provisions of this subsection. In issuing such regula-
 34 tions, the Secretary—

35 “(A) shall take into consideration disclosure for-
 36 mats used by existing interstate Internet seller certifi-
 37 cation programs; and

1 “(B) shall in defining the term ‘place of business’
 2 include provisions providing that such place is a single
 3 location at which employees of the business perform job
 4 functions, and not a post office box or similar locale.”.

5 (b) PROHIBITED ACTS.—Section 301 of the Federal Food,
 6 Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding
 7 at the end the following:

8 “(bb) The failure to post information required under sec-
 9 tion 503B(b)(2) or for knowingly making a materially false
 10 statement when posting such information as required under
 11 such section or violating section 503B(b)(4).”.

12 **SEC. 913. PUBLIC EDUCATION.**

13 The Secretary of Health and Human Services shall engage
 14 in activities to educate the public about the dangers of pur-
 15 chasing prescription drugs from unlawful Internet sources. The
 16 Secretary should educate the public about effective public and
 17 private sector consumer protection efforts, as appropriate, with
 18 input from the public and private sectors, as appropriate.

19 **SEC. 914. STUDY REGARDING COORDINATION OF REGU-**
 20 **LATORY ACTIVITIES.**

21 Not later than 180 days after the date of enactment of
 22 this Act, the Secretary of Health and Human Services, after
 23 consultation with the Attorney General, shall submit to Con-
 24 gress a report providing recommendations for coordinating the
 25 activities of Federal agencies regarding interstate Internet sell-
 26 ers that operate from foreign countries and for coordinating the
 27 activities of the Federal Government with the activities of gov-
 28 ernments of foreign countries regarding such interstate Inter-
 29 net sellers.

30 **SEC. 915. EFFECTIVE DATE.**

31 The amendments made by this subtitle shall take effect 1
 32 year after the date of enactment of this Act, except that the
 33 authority of the Secretary of Health and Human Services to
 34 commence the process of rulemaking is effective on the date of
 35 enactment of this Act.

Subtitle C—Promotion of Electronic Prescription

SEC. 921. PROGRAM OF GRANTS TO HEALTH CARE PROVIDERS TO IMPLEMENT ELECTRONIC PRESCRIPTION DRUG PROGRAMS.

Part P of title III of the Public Health Service Act is amended by inserting after section 399N the following new section:

“SEC. 399O. GRANTS TO HEALTH CARE PROVIDERS TO IMPLEMENT ELECTRONIC PRESCRIPTION DRUG PROGRAMS

“(a) IN GENERAL.—The Secretary is authorized to make grants for the purpose of assisting health care providers who prescribe drugs and biologicals in implementing electronic prescription programs described in section 1860C(d)(3) of the Social Security Act.

“(b) APPLICATION.—No grant may be made under this section except pursuant to a grant application that is submitted in a time, manner, and form approved by the Secretary.

“(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fiscal year 2004, such sums as may be appropriate to carry out this section.”.

Subtitle D—Treatment of Rare Diseases

SEC. 931. NIH OFFICE OF RARE DISEASES AT NATIONAL INSTITUTES OF HEALTH.

Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.), as amended by Public Law 107–84, is amended by inserting after section 404E the following:

“OFFICE OF RARE DISEASES

“SEC. 404F. (a) ESTABLISHMENT.—There is established within the Office of the Director of NIH an office to be known as the Office of Rare Diseases (in this section referred to as the ‘Office’), which shall be headed by a Director (in this section referred to as the ‘Director’), appointed by the Director of NIH.

“(b) DUTIES.—

1 “(1) IN GENERAL.—The Director of the Office shall
2 carry out the following:

3 “(A) The Director shall recommend an agenda for
4 conducting and supporting research on rare diseases
5 through the national research institutes and centers.
6 The agenda shall provide for a broad range of research
7 and education activities, including scientific workshops
8 and symposia to identify research opportunities for rare
9 diseases.

10 “(B) The Director shall, with respect to rare dis-
11 eases, promote coordination and cooperation among the
12 national research institutes and centers and entities
13 whose research is supported by such institutes.

14 “(C) The Director, in collaboration with the direc-
15 tors of the other relevant institutes and centers of the
16 National Institutes of Health, may enter into coopera-
17 tive agreements with and make grants for regional cen-
18 ters of excellence on rare diseases in accordance with
19 section 404G.

20 “(D) The Director shall promote the sufficient al-
21 location of the resources of the National Institutes of
22 Health for conducting and supporting research on rare
23 diseases.

24 “(E) The Director shall promote and encourage
25 the establishment of a centralized clearinghouse for
26 rare and genetic disease information that will provide
27 understandable information about these diseases to the
28 public, medical professionals, patients and families.

29 “(F) The Director shall biennially prepare a re-
30 port that describes the research and education activities
31 on rare diseases being conducted or supported through
32 the national research institutes and centers, and that
33 identifies particular projects or types of projects that
34 should in the future be conducted or supported by the
35 national research institutes and centers or other enti-
36 ties in the field of research on rare diseases.

“(G) The Director shall prepare the NIH Director’s annual report to Congress on rare disease research conducted by or supported through the national research institutes and centers.

“(2) PRINCIPAL ADVISOR REGARDING ORPHAN DISEASES.—With respect to rare diseases, the Director shall serve as the principal advisor to the Director of NIH and shall provide advice to other relevant agencies. The Director shall provide liaison with national and international patient, health and scientific organizations concerned with rare diseases.

“(c) DEFINITION.—For purposes of this section, the term ‘rare disease’ means any disease or condition that affects less than 200,000 persons in the United States.

“(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and \$4,000,000 for each of the fiscal years 2003 through 2006.”.

SEC. 932. RARE DISEASE REGIONAL CENTERS OF EXCELLENCE.

Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.), as amended by section 1021, is further amended by inserting after section 404F the following:

“RARE DISEASE REGIONAL CENTERS OF EXCELLENCE

“SEC. 404G. (a) COOPERATIVE AGREEMENTS AND GRANTS.—

“(1) IN GENERAL.—The Director of the Office of Rare Diseases (in this section referred to as the ‘Director’), in collaboration with the directors of the other relevant institutes and centers of the National Institutes of Health, may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for regional centers of excellence for clinical research into, training in, and demonstra-

tion of diagnostic, prevention, control, and treatment methods for rare diseases.

“(2) POLICIES.—A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH.

“(b) COORDINATION WITH OTHER INSTITUTES.—The Director shall coordinate the activities under this section with similar activities conducted by other national research institutes, centers and agencies of the National Institutes of Health and by the Food and Drug Administration to the extent that such institutes, centers and agencies have responsibilities that are related to rare diseases.

“(c) USES FOR FEDERAL PAYMENTS UNDER COOPERATIVE AGREEMENTS OR GRANTS.—Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

“(1) staffing, administrative, and other basic operating costs, including such patient care costs as are required for research;

“(2) clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public with respect to rare diseases; and

“(3) clinical research and demonstration programs.

“(d) PERIOD OF SUPPORT; ADDITIONAL PERIODS.—Support of a center under subsection (a) may be for a period of not to exceed 5 years. Such period may be extended by the Director for additional periods of not more than 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

“(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fis-

1 cal year 2002, and \$20,000,000 for each of the fiscal years
2 2003 through 2006.”.

3 **Subtitle E—Other Provisions** 4 **Relating to Drugs**

5 **SEC. 941. GAO STUDY REGARDING DIRECT-TO-CON-** 6 **SUMER ADVERTISING OF PRESCRIPTION** 7 **DRUGS.**

8 (a) IN GENERAL.—The Comptroller General of the United
9 States shall conduct a study for the purpose of determining—

10 (1) whether and to what extent there have been in-
11 creases in utilization rates of prescription drugs that are
12 attributable to guidance regarding direct-to-consumer ad-
13 vertising of such drugs that has been issued by the Food
14 and Drug Administration under section 502(n) of the Fed-
15 eral Food, Drug, and Cosmetic Act; and

16 (2) if so, whether and to what extent such increased
17 utilization rates have resulted in increases in the costs of
18 public or private health plans, health insurance, or other
19 health programs.

20 (b) CERTAIN DETERMINATIONS.—The study under sub-
21 section (a) shall include determinations of the following:

22 (1) The extent to which advertisements referred to in
23 such subsection have resulted in effective consumer edu-
24 cation about the prescription drugs involved, including an
25 understanding of the risks of the drugs relative to the bene-
26 fits.

27 (2) The extent of consumer satisfaction with such ad-
28 vertisements.

29 (3) The extent of physician satisfaction with the ad-
30 vertisements, including determining whether physicians be-
31 lieve that the advertisements interfere with the exercise of
32 their medical judgment by influencing consumers to prefer
33 advertised drugs over alternative therapies.

34 (4) The extent to which the advertisements have re-
35 sulted in increases in health care costs for taxpayers, for
36 employers, or for consumers due to consumer decisions to

1 seek advertised drugs rather than lower-costs alternative
2 therapies.

3 (5) The extent to which the advertisements have re-
4 sulted in decreases in health care costs for taxpayers, for
5 employers, or for consumers due to decreased hospitaliza-
6 tion rates, fewer physician visits (not related to hospitaliza-
7 tion), lower treatment costs, or reduced instances of em-
8 ployee absences to care for family members with diseases
9 or disorders.

10 (c) REPORT.—Not later than two years after the date of
11 the enactment of this Act, the Comptroller General of the
12 United States shall submit to the Congress a report providing
13 the findings of the study under subsection (a).

14 **SEC. 942. CERTAIN HEALTH PROFESSIONS PROGRAMS**
15 **REGARDING PRACTICE OF PHARMACY.**

16 Part E of title VII of the Public Health Service Act (42
17 U.S.C. 294n et seq.) is amended by adding at the end the fol-
18 lowing subpart:

19 **“Subpart 3—Pharmacist Workforce Programs**

20 **“SEC. 771. PUBLIC SERVICE ANNOUNCEMENTS.**

21 **“(a) PUBLIC SERVICE ANNOUNCEMENTS.—**

22 **“(1) IN GENERAL.—**The Secretary shall develop and
23 issue public service announcements that advertise and pro-
24 mote the pharmacist profession, highlight the advantages
25 and rewards of being a pharmacist, and encourage individ-
26 uals to enter the pharmacist profession.

27 **“(2) METHOD.—**The public service announcements de-
28 scribed in subsection (a) shall be broadcast through appro-
29 priate media outlets, including television or radio, in a
30 manner intended to reach as wide and diverse an audience
31 as possible.

32 **“(b) STATE AND LOCAL PUBLIC SERVICE ANNOUNCE-**
33 **MENTS.—**

34 **“(1) IN GENERAL.—**The Secretary shall award grants
35 to entities to support State and local advertising campaigns
36 through appropriate media outlets to promote the phar-
37 macist profession, highlight the advantages and rewards of

1 being a pharmacist, and encourage individuals to enter the
2 pharmacist profession.

3 “(2) USE OF FUNDS.—An entity that receives a grant
4 under subsection (a) shall use funds received through such
5 grant to acquire local television and radio time, place ad-
6 vertisements in local newspapers, and post information on
7 billboards or on the Internet, in order to—

8 “(A) advertise and promote the pharmacist profes-
9 sion;

10 “(B) promote pharmacist education programs;

11 “(C) inform the public of public assistance regard-
12 ing such education programs;

13 “(D) highlight individuals in the community that
14 are presently practicing as pharmacists to recruit new
15 pharmacists; and

16 “(E) provide any other information to recruit indi-
17 viduals for the pharmacist profession.

18 “(3) METHOD.—The campaigns described in sub-
19 section (a) shall be broadcast on television or radio, placed
20 in newspapers as advertisements, or posted on billboards or
21 the Internet, in a manner intended to reach as wide and
22 diverse an audience as possible.

23 **“SEC. 772. DEMONSTRATION PROJECT.**

24 “(a) IN GENERAL.—The Secretary shall establish a dem-
25 onstration project to enhance the participation of individuals
26 who are pharmacists in the National Health Service Corps
27 Loan Repayment Program described in section 338B.

28 “(b) SERVICES.—Services that may be provided by phar-
29 macists pursuant to the demonstration project established
30 under this section include medication therapy management
31 services to assure that medications are used appropriately by
32 patients, to enhance patients’ understanding of the appropriate
33 use of medications, to increase patients’ adherence to prescrip-
34 tion medication regimens, to reduce the risk of adverse events
35 associated with medications, and to reduce the need for other
36 costly medical services through better management of medica-
37 tion therapy. Such services may include case management, dis-

1 ease management, drug therapy management, patient training
2 and education, counseling, drug therapy problem resolution,
3 medication administration, the provision of special packaging,
4 or other services that enhance the use of prescription medica-
5 tions.

6 “(c) PROCEDURE.—The Secretary may not provide assist-
7 ance to an individual under this section unless the individual
8 agrees to comply with all requirements described in sections
9 338B and 338D.

10 “(d) LIMITATIONS.—The demonstration project described
11 in this section shall provide for the participation of—

12 “(1) individuals to provide services in rural and urban
13 areas; and

14 “(2) enough individuals to allow the Secretary to prop-
15 erly analyze the effectiveness of such project.

16 “(e) DESIGNATIONS.—The demonstration project de-
17 scribed in this section, and any pharmacists who are selected
18 to participate in such project, shall not be considered by the
19 Secretary in the designation of a health professional shortage
20 area under section 332 during fiscal years 2003 through 2005.

21 “(f) RULE OF CONSTRUCTION.—This section shall not be
22 construed to require any State to participate in the project de-
23 scribed in this section.

24 “(g) REPORT.—The Secretary shall prepare and submit a
25 report on the project to—

26 “(A) the Committee on Health, Education, Labor,
27 and Pensions of the Senate;

28 “(B) the Subcommittee on Labor, Health and
29 Human Services, and Education of the Committee on
30 Appropriations of the Senate;

31 “(C) the Committee on Energy and Commerce of
32 the House of Representatives; and

33 “(D) the Subcommittee on Labor, Health and
34 Human Services, and Education of the Committee on
35 Appropriations of the House of Representatives.

1 **“SEC. 773. INFORMATION TECHNOLOGY.**

2 “(a) GRANTS AND CONTRACTS.—The Secretary may make
3 awards of grants or contracts to qualifying schools of pharmacy
4 for the purpose of assisting such schools in acquiring and in-
5 stalling computer-based systems to provide pharmaceutical edu-
6 cation. Education provided through such systems may be grad-
7 uate education, professional education, or continuing education.
8 The computer-based systems may be designed to provide on-site
9 education, or education at remote sites (commonly referred to
10 as distance learning), or both.

11 “(b) QUALIFYING SCHOOL OF PHARMACY.—For purposes
12 of this section, the term ‘qualifying school of pharmacy’ means
13 a school of pharmacy (as defined in section 799B) that requires
14 students to serve in a clinical rotation in which pharmacist
15 services are part of the curriculum.

16 **“SEC. 774. AUTHORIZATION OF APPROPRIATIONS.**

17 “For the purpose of carrying out this subpart, there are
18 authorized to be appropriated such sums as may be necessary
19 for each of the fiscal years 2003 through 2006.”.

20 **TITLE X—HEALTH-CARE RELATED**
21 **TAX PROVISIONS**

22 **SEC. 1001. ELIGIBILITY FOR ARCHER MSA’S EXTENDED**
23 **TO ACCOUNT HOLDERS OF**
24 **MEDICARE+CHOICE MSA’S.**

25 (a) IN GENERAL.—Subparagraph (B) of section 220(c)(2)
26 of the Internal Revenue Code of 1986 is amended by adding
27 at the end the following new clause:

28 “(iii) MEDICARE+CHOICE MSA’S.—In the case
29 of an individual who is covered under an MSA plan
30 (as defined in section 1859(b)(3) of the Social Se-
31 curity Act) which such individual elected under sec-
32 tion 1851(a)(2)(B) of such Act—

33 “(I) such plan shall be treated as a high
34 deductible health plan for purposes of this sec-
35 tion,

“(II) subsection (b)(2)(A) shall be applied by substituting ‘100 percent’ for ‘65 percent’ with respect to such individual,

“(III) with respect to such individual, the limitation under subsection (d)(1)(A)(ii) shall be 100 percent of the highest annual deductible limitation under section 1859(b)(3)(B) of the Social Security Act,

“(IV) paragraphs (4), (5), and (7) of subsection (b) and paragraph (1)(A)(iii) of this subsection shall not apply with respect to such individual, and

“(V) the limitation which would (but for this subclause) apply under subsection (b)(1) with respect to such individual for any taxable year shall be reduced (but not below zero) by the amount which would (but for subsection 106(b)) be includible in such individual’s gross income for the taxable year.”.

(b) ACCOUNTS NOT COUNTED AGAINST NUMERICAL LIMITS.—

(1) IN GENERAL.—Paragraph (3) of section 220(j) of such Code is amended—

(A) in the heading, by striking “PREVIOUSLY UNINSURED” and inserting “CERTAIN”,

(B) in subparagraph (A), by striking “by not counting the Archer MSA of any previously uninsured individual.” and inserting “by not counting—

“(i) the Archer MSA of any previously uninsured individual, and

“(ii) the Archer MSA of any eligible individual who qualifies as such an individual by reason of subsection (c)(2)(B)(iii).”.

(2) REPORTING REQUIREMENT.—Subparagraph (A) of section 220(j)(4) of such Code is amended in clause (ii) by striking “and” at the end, in clause (iii) by striking the pe-

riod and inserting “, and”, and by adding at the end the following new clause:

“(iv) the number of such accounts which are accounts of eligible individuals who qualify as such individuals by reason of subsection (c)(2)(B)(iii).”.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2002.

SEC. 1002. ADJUSTMENT OF EMPLOYER CONTRIBUTIONS TO COMBINED BENEFIT FUND TO REFLECT MEDICARE PRESCRIPTION DRUG SUBSIDY PAYMENTS.

Section 9704(b) of the Internal Revenue Code of 1986 (relating to health benefit premium) is amended by adding at the end the following new paragraph:

“(4) ADJUSTMENTS FOR MEDICARE PRESCRIPTION DRUG SUBSIDIES.—The trustees of the Combined Fund shall decrease the per beneficiary premium for each plan year in which a subsidy payment is provided to it under section 1860H of the Social Security Act by the amount which would place the Combined Fund in the same financial position as if such subsidy payment had not been received.”.

SEC. 1003. EXPANSION OF HUMAN CLINICAL TRIALS QUALIFYING FOR ORPHAN DRUG CREDIT.

(a) IN GENERAL.—Paragraph (2) of section 45C(b) of the Internal Revenue Code of 1986 is amended by adding at the end the following new subparagraph:

“(C) TREATMENT OF CERTAIN EXPENSES INCURRED BEFORE DESIGNATION.—For purposes of subparagraph (A)(ii)(I), if a drug is designated under section 526 of the Federal Food, Drug, and Cosmetic Act not later than the due date (including extensions) for filing the return of tax under this subtitle for the taxable year in which the application for such designation of such drug was filed, such drug shall be treated as having been designated on the date that such application was filed.”.

1 (b) EFFECTIVE DATE.—The amendment made by sub-
2 section (a) shall apply to expenses incurred after the date of
3 the enactment of this Act.

